

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

U.S. Patent No. 6,673,838

Inventors:

HADFIELD, Anthony F. et al.

Issue Date:

January 6, 2007

For:

SUCCINATE SALT OF O-DESMETHYL-VENLAFAXINE

Assignee:

Wyeth

Date:

April 25, 2008

Mail Stop Hatch-Waxman PTE Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

APPLICATION FOR EXTENSION OF PATENT TERM UNDER 35 U.S.C. §156

Commissioner for Patents:

Applicant, Wyeth, a corporation organized and existing under the laws of Delaware, and having a principal place of business at 5 Giralda Farms, Madison, NJ 07490, represents that it is the owner of the entire interest in and to U.S. Patent No. 6,673,838, granted to Anthony Francis Hadfield, Syed M. Shah, Michael W. Winkley, Karen W. Sutherland, James A. Provost, Aeri Park, Rex A. Shiplett, Brenton W. Russell, and Beat T. Weber for "Succinate Salt of O-desmethyl-venlafaxine," as reflected in the various assignment documents recorded by the U.S. Patent and Trademark Office on August 27, 2001 at Reel 012126, Frame 0893, on August 27, 2001 at Reel 012127, Frame 0102, on April 12, 2002 at Reel 012828, Frame 0928, on July 30, 2002 at Reel 013121, Frame 0837, on July 30, 2002 at Reel 013121, Frame 0855, on July 31, 2002 at Reel 013127, Frame 0287, on July 31, 2002 at Reel 013127, Frame 0306, on August 1, 2002 at Reel 013130, Frame 0479, and on August 21, 2002 at Reel 013229, Frame 0864. Attached at Exhibit A is a Power of Attorney document appointing the undersigned patent attorney as legal representative of Applicant.

U.S. Patent No. 6,673,838 Transmittal Application for Extension of Patent

The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 50-1349.

By:

Respectfully submitted,

HOGAN & HARTSON LLP

Dated: April 25, 2008

HOGAN & HARTSON LLP

555 Thirteenth Street, N.W. Washington, D.C. 20004

Telephone: 202-637-5703 Facsimile: 202-637-5910

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Customer No. 24633

Celine Jimenez Crowson Registration No. 40,357

Kevin G. Shaw

Registration No. 43,110

Wyeth Pharmaceuticals is a wholly owned division of Wyeth and has a principal place of business at 5 Giralda Farms, Madison, NJ 07490. Wyeth Pharmaceuticals is the owner of a New Drug Application ("NDA") for PRISTIQTM, NDA number NDA 21-966. Attached at **Exhibit A** is a Power of Attorney document appointing the undersigned patent attorney as legal representative of Applicant and as agent of Wyeth and its division Wyeth Pharmaceuticals for purposes of requesting and/or obtaining any patent term extensions with respect to NDA number 21-966.

Applicant, acting through its duly authorized attorney, hereby submits this application for extension of patent term under 35 U.S.C. §156, based upon the approval by the Food and Drug Administration for commercial marketing or use of PRISTIQ™, since the active ingredient of PRISTIQ™ is desvenlafaxine succinate, which falls within the ambit of the claims of U.S. Patent No. 6,673,838. The information contained in this Application and its Exhibits is provided in accordance with the rules promulgated by the U.S. Patent and Trademark Office at 37 CFR §§1.710-1.785 and presented in the manner set forth at 37 CFR §1.740.

1. <u>A Complete Identification Of The Approved Product As By Appropriate Chemical And Generic Name, Physical Structure Or Characteristics</u>

The approved product, PRISTIQTM, contains desvenlafaxine succinate as its active ingredient. The chemical name of desvenlafaxine (also known as O-desmethyl venlafaxine) is RS-4-[2-dimethylamino-1-(1-hydroxycyclohexyl)ethyl]phenol and has the empirical formula $C_{16}H_{25}NO_2$. Desvenlafaxine succinate is a succinate salt of desvenlafaxine, and has the empirical formula $C_{16}H_{25}NO_2 \cdot C_4H_6O_4$ ($C_{16}H_{25}NO_2 \cdot C_4H_6O_4 \cdot H_2O$ for the monohydrate). Desvenlafaxine succinate monohydrate has a molecular weight of 399.48, and the following structural formula:

Desvenlafaxine succinate is prepared as a white to off-white powder that is soluble in water (pH dependent), with an octanol:aqueous system (at pH 7.0) partition coefficient of 0.21. The approved product is formulated as an extended release tablet for once daily oral administration, and is available in tablet strengths of 50 mg and 100 mg. Each PRISTIQTM tablet contains either 76 mg or 152 mg of desvenlafaxine succinate monohydrate, which is equivalent to 50 mg or 100 mg, respectively, of desvenlafaxine.

2. A Complete Identification Of The Federal Statute Including The Applicable Provisions Of Law Under Which The Regulatory Review Occurred

The approved product, PRISTIQ™, was subject to regulatory review under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §355).

3. An Identification Of The Date On Which The Product Received Permission For Commercial Marketing Or Use Under The Provision Of Law Under Which The Applicable Regulatory Review Period Occurred

The approved product, PRISTIQTM, received permission for commercial marketing or use under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §355) on February 29, 2008. A copy of a letter from the Food and Drug Administration ("FDA") indicating the date of approval is attached hereto at **Exhibit B**.

4. In The Case Of A Drug Product, An Identification Of Each Active Ingredient In The Product And As To Each Active Ingredient, A Statement That It Has Not Been Previously Approved For Commercial Marketing Or Use Under The Federal Food, Drug, and Cosmetic Act, The Public Health Service Act, Or The Virus-Serum-Toxin Act, Or A Statement Of When The Active Ingredient Was Approved For Commercial Marketing Or Use (Either Alone Or In Combination With Other Active Ingredients), The Use For Which It Was Approved, And The Provision Of Law Under Which It Was Approved

The active ingredient in PRISTIQTM is desvenlafaxine succinate, which has not been previously approved for commercial marketing or use under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Virus-Serum-Toxin Act.

5. A Statement That The Application Is Being Submitted Within The Sixty Day
Period Permitted For Submission Pursuant to 37 CFR §1.720(f) And An
Identification Of The Date Of The Last Day On Which The Application Could Be
Submitted

This application is being submitted within the permitted sixty (60) day period, the last day of which is April 28, 2008.

6. A Complete Identification Of The Patent For Which An Extension Is Being Sought By The Name Of The Inventor, The Patent Number, The Date Of Issue, And The Date Of Expiration

The complete identification of the patent for which extension is sought is:

Inventors:

Anthony F. Hadfield

Syed M. Shah

Michael W. Winkley Karen W. Sutherland James A. Provost

Aeri Park

Rex A. Shiplett Brenton W. Russell Beat T. Weber

Patent Number:

6,673,838

Issue Date:

January 6, 2004

Expiration Date:

February 11, 2022 (without extension under 35 U.S.C. §156)

7. A Copy Of The Patent For Which An Extension Is Being Sought, Including The Entire Specification (Including Claims) And Drawings

A complete copy of U.S. Patent No. 6,673,838 is annexed as Exhibit C.

8. A Copy Of Any Disclaimer, Certificate of Correction, Receipt Of Maintenance Fee Payment, Or Reexamination Certificate Issued In The Patent

The patent for which extension is being sought has not been the subject of any disclaimer, certificate of correction, or reexamination certificate. The first maintenance fee was duly paid on June 21, 2007 by Applicant, and no additional maintenance fees are due at this time. A copy of the maintenance fee statement evidencing this status is annexed as **Exhibit D**.

9. A Statement That The Patent Claims The Approved Product Or A Method Of
Using Or Manufacturing The Approved Product, And A Showing Which Lists
Each Applicable Patent Claim And Demonstrates The Manner In Which At Least
One Such Patent Claim Reads On The Approved Product Or Method Of Using Or
Manufacturing The Approved Product

U.S. Patent No. 6,673,838 claims the approved product, PRISTIQ™. More specifically, claims 1-7 and 22 read on the approved product and claim the active ingredient of the final approved product desvenlafaxine succinate, claims 23, 25-34, and 46 read on the approved product and claim pharmaceutical compositions comprising desvenlafaxine succinate, and claims 35 and 45 read on a methods that comprise using desvenlafaxine succinate for treatment. Claim 1 is compared to the approved product in the table below.

	Pate	ent Clair	Approved Product	
l. ven			 O-desmethyl	The active ingredient of the approved product is desvenlafaxine succinate, which is also known as and is
				identical to O-desmethyl venlafaxine succinate.

10. A Statement, Beginning On A New Page, Of The Relevant Dates And Information Pursuant To 35 U.S.C. § 156(g) In Order To Enable The Secretary Of Agriculture, As Appropriate, To Determine The Applicable Regulatory Review Period As Follows (i): For A Patent Claiming A Human Drug Product, Antibiotic, Or Human Biological Product, The Effective Date Of The Investigational New Drug (IND) Application And The IND Number; The Date On Which A New Drug Application (NDA) Or A Product License Application (PLA) Was Initially Submitted And The NDA Or PLA Number And The Date On Which The NDA Was Approved Or The Product License Issued

Wyeth was notified via teleconference with the FDA on May 9, 2002 that that the IND (IND 64,552) for desvenlafaxine succinate was in effect, and received a letter from the FDA confirming the IND became effective on June 11, 2002. For purposes of this application for patent term extension, the Applicant is entitled to an IND date of at least as early as June 11, 2002. The NDA (NDA 21-966) for PRISTIQ[™] was initially submitted to the Food and Drug Administration on December 22, 2005 and was approved on February 29, 2008.

11. A Brief Description Beginning On A New Page OF The Significant Activities

Undertaken By The Marketing Applicant During The Applicable Regulatory

Review Period With Respect To The Approved Product And The Significant

Dates Applicable To Such Activities

A brief description of significant activities undertaken by the marketing applicant during the regulatory review period with respect to the approved product in annexed as **Exhibit**E. This exhibit provides a chronology of the major communications between the marketing applicant and the Food and Drug Administration, including a brief summary of the subject matter and date of these communications.

Applicant reserves the right to supplement the chronology of **Exhibit E** with materials from which it was derived or other evidence related to Applicant's conduct in obtaining the approval of PRISTIQTM. See, e.g., 21 CFR § 60.32.

12. A Statement Beginning On A New Page That In The Opinion Of The Applicant
The Patent Is Eligible For The Extension And A Statement As To The Length Of
The Extension Claimed, Including How The Length Of Extension Was
Determined

Applicant is of the opinion that U.S. Patent No. 6,673,838 is eligible for extension under 35 U.S.C. § 156, because it satisfies all of the requirements for such extension as follows:

a. <u>35 U.S.C. §156(a)</u>; 37 CFR §1.720(a)

U.S. Patent No. 6,673,838 claims a product, and a method of using a product.

b. <u>35 U.S.C. §156(a)(1); 37 CFR §1.720(g)</u>

The term of U.S. Patent No. 6,673,838 has not expired before submission of this application.

c. <u>35 U.S.C. §156(a)(2); 37 CFR §1.720(b)</u>

The term of U.S. Patent No. 6,673,838 has never previously been extended under 35 U.S.C. §156.

d. 35 U.S.C. §156(a)(3); 37 CFR §1.730

This application for extension is submitted by the authorized agent or the owner of record in accordance with the requirement of 35 U.S.C. §156(d) and the rules of the U.S. Patent and Trademark Office.

e. <u>35 U.S.C. §156(a)(4); 37 CFR §1.720(d)</u>

The product PRISTIQ[™] has been subject to a regulatory review period as defined in 35 U.S.C. §156(g) before its commercial marketing or use.

f. 35 U.S.C. §156(a)(5)(A); 37 CFR §1.720(e)(i)

The commercial marketing or use of the product PRISTIQ™ after the regulatory review period is the first permitted commercial marketing or use of the product under the provision of the Federal Food, Drug, and Cosmetics Act (21 U.S.C. §360) under which such regulatory review period occurred.

g. <u>35 U.S.C. §156(c)(4); 37 CFR §1.720(h)</u>

No other patent has been extended for the same regulatory review period for the product PRISTIQTM.

h. 35 U.S.C. §156(d)(1); 37 CFR §1.720(f)

This application is submitted within the permitted 60 day period beginning on the date the product first received permission for commercial marketing or use.

Applicant is of the opinion that U.S. Patent No. 6,673,838 is eligible for extension under 35 U.S.C. § 156 for 17 days, as determined pursuant to 37 CFR §1.775 as follows:

Patent Information:

Patent Issue Date January 6, 2004

Earliest non-provisional priority date February 11, 2002

Days Extension under 35 U.S.C. 154(b) 0

FDA Information:

Latest Date IND Becomes Effective June 11, 2002

Date NDA Submitted to the FDA December 22, 2005

Date NDA Approved by the FDA February 29, 2008

IND Period:

Latest Start Date of Regulatory Review Period	June 11, 2002
IND Review Period (days)	1290
½ IND Review Period (days)	645

Regulatory Review Period Allowed:

NDA Review Period (days)	800
Regulatory Review Period (days)	2090
Reg. Rev. Period less ½ IND period (days)	1445

Statutory Limitations:

Patent Expiration Date (20 year term)	February 11, 2022
Expiration under 5 year extension limitation (Date 1)	February 11, 2027
Expiration under 14 from NDA approval limitation (Date 2)	February 28, 2022
Expiration based upon full review period (Date 3)	January 26, 2026
Final Expiration Date (Earliest of Date 1, Date 2, or Date 3)	February 28, 2022
Maximum Extension in Days:	17

13. A Statement That Applicant Acknowledges A Duty To Disclose To The Commissioner Of Patents And Trademarks And The Secretary Of Health And Human Services Any Information Which Is Material To The Determination Of Entitlement To The Extension Sought

Applicant acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services any information which is material to any determinations of entitlement to the extension sought in the Application.

14. The Prescribed Fee For Receiving And Acting Upon The Application For Extension

The prescribed fee pursuant to 37 CFR §1.20(j) for receiving and acting upon this application is to be charged to the Deposit Account of Applicant's undersigned attorney as authorized in the attached letter, which is submitted in triplicate.

15. The Name, Address, And Telephone Number Of The Person To Whom Inquiries And Correspondence Relating To The Application For Patent Term Extension Are To Be Directed

Please address all correspondence to:

Kevin G. Shaw Hogan & Hartson, LLP 555 Thirteenth St., NW Washington, DC 20004

16. A Duplicate Of The Application Papers, Certified As Such

Applicant hereby certifies that this application for extension is being filed in triplicate.

17. An Oath Or Declaration

Applicant, through its undersigned patent attorney authorized to practice before the Patent and Trademark Office and who has general authority from the agent or owner to act on behalf of the agent or owner in patent matters, being duly warned that willful false statements are punishable by fine or imprisonment or both under section 1001 of Title 18, United States Code and that willful false statements and the like may jeopardize the validity of this application and the patent to which it relates, states and declares that the following statements made based on his own knowledge are true and that all statements made on information and belief are believed to be true:

- (1) The undersigned is registered to practice before the Patent and Trademark

 Office and is making this declaration as a patent attorney who has general
 authority to act on behalf of the applicant in patent matters.
- (2) The undersigned has reviewed and understands the contents of the application being submitted pursuant to this section;
- (3) The undersigned believes the patent is subject to an extension pursuant to 37 C.F.R. § 1.710 in the event of NDA approval and, in the interim, is subject to an extension pursuant to 37 C.F.R. § 1.790;

(4) The undersigned believes an extension of the length claimed is justified

under 35 U.S.C. 156 and the applicable regulations; and

(5) The undersigned believes the patent for which extension is being sought

meets the conditions for extension of the term of a patent as set forth in 37

C.F.R. § 1.720 in the event of NDA approval, and meets the requirements

for an interim extension of a patent set forth in 37 C.F.R. § 1.790.

If this application for extension of patent term is held to be informal, applicant

may seek to have that holding reviewed by filing a petition with the required fee, as necessary,

pursuant to 37 C.F.R. §§ 1.181, 1.182 or 1.183, as appropriate, within such time as may be set in

any notice that the application has been held to be informal, or if no time is set, within one month

of the date on which the application was held informal.

Respectfully submitted,

Dated: April 25, 2008

HOGAN & HARTSON LLP

555 13th Street, N.W.

Washington, D.C. 20004 Telephone: 202-637-5600

Facsimile: 202-637-5910

Email: kgshaw@hhlaw.com

Customer No.: 24633

Kevin G. Shaw

Kegistration No. 43,110

Exhibit A



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

U.S. Patent No. 6,673,838

Inventors: HADFIELD, Anthony F. et al.

Issue Date: January 6, 2007

For: SUCCINATE SALT OF O-DESMETHYL-VENLAFAXINE

Assignee: Wyeth

POWER OF ATTORNEY FOR PATENT TERM EXTENSION APPLICATION

Wyeth, a corporation organized and existing under the laws of Delaware, and having a principal place of business at 5 Giralda Farms, Madison, NJ 07490, is the sole owner of the entire interest in and to U.S. Patent No. 6,673,838 as reflected in the various assignment documents recorded by the U.S. Patent and Trademark Office on August 27, 2001 at Reel 012126, Frame 0893, on August 27, 2001 at Reel 012127, Frame 0102, on April 12, 2002 at Reel 012828, Frame 0928, on July 30, 2002 at Reel 013121, Frame 0837, on July 30, 2002 at Reel 013121, Frame 0855, on July 31, 2002 at Reel 013127, Frame 0287, on July 31, 2002 at Reel 013127, Frame 0306, on August 1, 2002 at Reel 013130, Frame 0479, and on August 21, 2002 at Reel 013229, Frame 0864.

Wyeth hereby revokes all previous powers of attorney and appoints Kevin G. Shaw and the registered practitioners of Hogan & Hartson, L.L.P. included in the Customer Number provided below to prosecute this patent term extension application and to transact all business in the Patent and Trademark Office connected therewith, and further directs that all correspondence be addressed to Kevin G. Shaw at that Customer Number.

U.S. Patent No. 6,673,838 Power of Attorney

The undersigned, acting in the official capacity stated below, has authority to does hereby execute this document on behalf of Wyeth.

Customer Number: 24633

Please direct all inquiries to:

Kevin G. Shaw

24 April 2008

Telephone: (202) 637-6466 Facsimile: (202) 637-5910

William King

Assistant Secretary

Wyeth

5 Giralda Farms Madison, NJ 07490 Date

Exhibit B



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration Rockville, MD 20857

5 2008 PDA 21-992

NDA APPROVAL

Wyeth Pharmaceuticals, Inc. Attention: Kenneth Bonk Director II, Global Regulatory Affairs P.O. Box 8299 Philadelphia, PA 19101-9822

Dear Mr. Bonk:

Please refer to your new drug application (NDA) dated and received on December 22, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pristiq (desvenlafaxine succinate) 50mg, and 100mg extended release tablets.

We acknowledge receipt of your submissions dated:

April 4, 2007	December 14, 2007	February 14, 2008
May 11, 2007	December 19, 2007	February 15, 2008
June 1, 2007	December 20, 2007	February 20, 2008
June 27, 2007	January 14, 2008	February 21, 2008
August 23, 2007	February 4, 2008	February 22, 2008
August 29, 2007	February 11, 2008	

The August 29, 2007 submission constituted a complete response to our January 22, 2007 action letter.

This new drug application provides for the use of Pristiq (desvenlafaxine succinate) tablets for the treatment of major depressive disorder.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert and Medication Guide). Upon receipt, we will transmit that version to the

National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-992."

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the submitted carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005). Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "Final Printed Carton and Container Labels for approved NDA 21-992." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

PEDIATRIC RESEARCH EQUITY ACT (PREA)

All applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable. We are waiving the pediatric study requirement for ages 0-6 years because the necessary studies are impossible or highly impracticable because there are not enough patients in that age group with the disease to study. We are deferring submission of your pediatric studies for ages 7-17 years because the drug is ready for approval for use in adults and the pediatric studies have not been completed.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of these postmarketing studies shall be reported annually according to 21 CFR 314.81. These commitments are listed below.

POSTMARKETING COMMITMENTS

We remind you of your following postmarketing study commitments agreed upon in your submission dated February 19, 2008. These commitments are listed below.

1. Deferred Pediatric Studies Under PREA

You have agreed to conduct studies to assess the safety and effectiveness of desvenlafaxine succinate as a treatment for Major Depressive Disorder in pediatric patients ages 7 to 17 (children and adolescents). Both children (ages 7 to 11 years) and adolescents (ages 12 to 17 years) will be equally represented in the samples, and there will be a reasonable distribution of both sexes in these age strata. You have agreed to submit the results of these studies no later than 4.5 years after the date of approval for this NDA.

Final Report Submission: 4.5 years from the date of approval

Submit final study reports to this NDA. For administrative purposes, all submissions related to this/these pediatric postmarketing study commitment(s) must be clearly designated "Required Pediatric Study Commitments".

2. Exploration of Dose Response for Effectiveness

Your NDA for desvenlafaxine succinate (DVS) demonstrates the effectiveness of doses as low as 50 mg as a treatment for Major Depressive Disorder (MDD), however, the available data for effectiveness for this drug in MDD suggests a flat dose response curve for efficacy between 50 and 400 mg/day. On the other hand, there is a clear dose response for adverse events as the dose increases from 50 to 400 mg/day. Therefore, there is a need to better understand the lower end of the dose response curve to determine if efficacy might be achieved at doses even lower than 50 mg/day. You have agreed to conduct and submit the results of a randomized controlled study including placebo and DVS doses of 10, 25, and 50 mg/day as a Postmarketing commitment. This study will assess efficacy in this dose range and will also include a validated and reliable outcome measure to assess for sexual dysfunction. You have agreed to submit the results of this trial no later than 3 years after the date of the approval for this NDA.

Final Report Submission: 3 years from the date of approval

3. Long-Term Efficacy Studies

Although your NDA for desvenlafaxine succinate demonstrates effectiveness of recommended doses (50-100 mg/day) as a treatment for Major Depressive Disorder over an interval of 8 weeks, it does not provide information about the duration and conditions of treatment with desvenlafaxine that are necessary to sustain its antidepressant effects over the full duration (likely 6 months to a year or longer) of an acute major depressive episode at these same recommended doses. While it is widely assumed that continued treatment of symptomatically remitted patients reduces their risk of relapse,

have no evidence that desvenlafaxine at these lower doses has efficacy after 8 weeks. Once you have established the lower end of the dose-response curve for efficacy, you have agreed to conduct and submit the results of a randomized withdrawal study to address longer-term efficacy for your drug at appropriate doses. If the lower dose study establishes that 50 mg/day is the lowest effective dose, this study will evaluate doses of 50 and 100 mg/day. You have agreed to submit the results of this trial no later than 3 years after the date of initiation, or approximately 5.5 years from the date of approval for this NDA..

Final Report Submission: 5.5 years from the date of approval

4. Sexual Dysfunction

While it is clear that desvenlafaxine has a qualitatively negative effect on sexual function from the adverse events collected during your earlier trials, we do not have quantified sexual dysfunction data. You have agreed to assess sexual dysfunction in your planned lower dose study. If the lower dose study establishes that 50 mg/day is the lowest effective dose, you have

agreed to conduct another acute, randomized controlled trial with placebo, 50, and 100 mg/day, and employ a validated and reliable outcome measure to assess for sexual dysfunction. This study could be conducted in parallel with the longer-term efficacy trial, and the results could be submitted approximately 5.5 years from the date of approval for this NDA.

Final Report Submission: 5.5 years from the date of approval

5. Pharmacology/Toxicology

Your combined fertility and embryo-fetal toxicity study in rats did not adequately assess desvenlafaxine's potential for embryo-fetal toxicity, including teratogenicity, due to decreased number of fetuses available for analysis at the high dose of 300 mg/kg. This appeared to result from effects of desvenlafaxine on fertility and pre-implantation loss and would not be factors if dosing were only done during the period of organogenesis. Consequently, you have agreed to conduct a standard embryo-fetal toxicity study in rats, and submit the results no later than 3 years after the date of the approval for this NDA.

Final Report Submission: 3 years from the date of approval

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments should be prominently labeled "Postmarketing Study Commitment Protocol", "Postmarketing Study Commitment Correspondence."

DISSOLUTION METHOD AND SPECIFICATION

Method: Apparatus: Speed: Medium: Temperature:	USP Apparatus 1 (baskets) 100 rpm 900 mL 0.9% NaCl in water 37°C ± 0.5°C
Specification: Time 2 hours 4 hours 8 hours 12 hours 24 hours	Criteria (% LC Released)

EXPIRY DATE

An expiration of 24 months has been granted.

ADVISORY COMMITTEE

NDA 21-992 was not referred to an advisory committee for review because there are several previously approved agents in the antidepressant class of drugs, evaluation of the safety data did not reveal particular safety issues that were unexpected for this class, and the design and results of the efficacy trials did not pose particular concerns.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration Center for Drug Evaluation and Research Division of Drug Marketing, Advertising, and Communications 5901-B Ammendale Road Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch Food and Drug Administration HFD-001, Suite 5100 5515 Security Lane Rockville, MD 20852

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

MEDWATCH-TO-MANUFACTURER PROGRAM

NDA 21-992 Page 6

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the program, please see the enrollment instructions and program description details at www.fda.gov/medwatch/report/mmp.htm.

If you have any questions, call Renmeet Grewal, Pharm.D., Regulatory Project Manager, at (301) 796-1080.

Sincerely,

{See appended electronic signature page}

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: Label & Medguide

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Robert Temple 2/29/2008 03:15:15 PM

Exhibit C

Exhibit D

UNITED STATES PATENT AND TRADEMARK OFFICE



Commissioner for Patents United States Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450 www.uspto.gov

Customer No 25291

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DATE PRINTED 04/23/2008

WYETH PATENT LAW GROUP 5 GIRALDA FARMS MADISON NJ 07940

MAINTENANCE FEE STATEMENT

According to the records of the U.S.Patent and Trademark Office (USPTO), the maintenance fee and any necessary surcharge have been timely paid for the patent listed below. The "PYMT DATE" column indicates the payment date (i.e., the date the payment was filed).

The payment shown below is subject to actual collection. If the payment is refused or charged back by a financial institution, the payment will be void and the maintenance fee and any necessary surcharge unpaid.

Direct any questions about this statement to: Mail Stop M Correspondence, Director of the USPTO, P.O.Box 1450, Alexandria, VA 22313-1450.

PATENT NUMBER	FEE AMT	SUR CHARGE	PYMT DATE	U.S. APPLICATION NUMBER	PATENT ISSUE DATE	APPL. FILING DATE	PAYMENT YEAR	SMALL ENTITY?	ATTY DKT NUMBER
6,673,838	\$900.00	\$0.00	06/21/07	10/073,743	01/06/04	02/11/02	04	NO	AM-100463

Exhibit E

Exhibit E

A brief description of significant activities undertaken by Wyeth during the regulatory review period for PRISTIQTM, together with applicable dates, follows below. A more detailed description of activities undertaken by Wyeth, including those listed below, is set forth in the IND Activities and NDA Activities tables produced on the pages following part 4 of this Exhibit.

1. Between June 11, 2002 and December 22, 2005, Wyeth conducted multiple clinical studies of PRISTIQTM. There were seven randomized, double-blind, placebo-controlled, fixed- and flexible-dose studies, one relapse prevention study, and three open-label, long-term safety studies. Wyeth also conducted at least 15 pharmacokinetic and pharmacodynamic studies.

2. Key Regulatory Dates

April 12, 2002	IND 64,552 submitted to FDA
May 9, 2002	FDA notification (via telephone) that IND is in effect
June 11, 2002	FDA letter confirming IND is in effect
February 4, 2003	Pre-Phase III meeting with FDA
April 10, 2003	End-of-Phase II/CMC meeting with FDA
November 6, 2003	Type C Meeting with FDA re: IVIVC
June 15, 2005	Meeting with FDA re: CMC Quality by Design (QbD)
September 20, 2005	Type C Meeting with FDA: CMC Pilot Program
September8, 2005	Pre-NDA meeting with FDA
October 27, 2005	Pre-NDA meeting with FDA re: CMC Issues
December 22, 2005	NDA 21-992 submitted to FDA
January 22, 2007	FDA action letter ("approvable")
August 29, 2007	Complete response to FDA action letter
February 29, 2008	FDA approval

3. Summary of Phase III Clinical Studies

There were seven randomized, double-blind, placebo-controlled, fixed- and flexible-dose studies, one relapse prevention study, and three open-label, long-term safety studies.

Start	Stop	Study (n=patients randomized)
September 2002	March 2003	Fixed-Dose Efficacy (n=227)
June 2003	August 2005	Relapse Prevention (n=603)
June 2003	May 2004	Flexible-Dose Efficacy (n=247)
August 2003	March 2006	Open-Label Flexible-Dose Safety (n=1408)
November 2003	November 2004	Fixed-Dose Efficacy (n=480)
November 2003	September 2004	Fixed-Dose Efficacy (n=375)
January 2004	May 2005	Open-Label Flexible-Dose Safety (n=108)
March 2004	May 2005	Flexible-Dose Efficacy (n=369)
April 2004	March 2005	Flexible-Dose Efficacy (n=369)
July 2004	May 2005	Flexible-Dose Efficacy (n=244)
October 2004	October 2005	Open-Label Flexible-Dose Safety (n=52)

4. Following the initial submission of the NDA on December 22, 2005, Wyeth submitted additional information to FDA on the following dates:

February 1, 2006 February 14, 2006 February 16, 2006 March 7, 2006 March 16, 2006 April 21, 2006 April 28, 2006 May 10, 2006 June 7, 2006 June 9, 2006 June 26, 2006 July 3, 2006 July 13, 2006 July 31, 2006 August 31, 2006 September 5, 2006

September 14, 2006 September 22, 2006 September 26, 2006 October 10, 2006 October 12, 2006 October 26, 2006 November 1, 2006 December 8, 2006 January 25, 2007 February 2, 2007 April 4, 2007 May 11, 2007 June 1, 2007 June 27, 2007 August 23, 2007 August 29, 2007

December 13, 2007 December 14, 2007 December 19, 2007 December 20, 2007 January 14, 2008 February 4, 2008 February 11, 2008 February 15, 2008 February 20, 2008 February 21, 2008 February 22, 2008 February 29, 2008

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Chronology Description		Current Specifications & Test Methods of Ventataxine HCL								Toxicology and Drug Metabolism Support for Phase 3 Ceinical Studies			New Protocol - Protocol No. 0600D3-186-US - DVS-233 SR - IND No. 64,552	DVS-233 SR - IND No. 64,552 - New Protocol #0600D3-223-US	New Protocol - DVS-233 SR - IND No. 64,552 - New Protocol #080003-223-PL				S./CNS/FDA/Dvs-233 SR/MD/S017 doc	S.ICNS/FDAIDM-233 SRIINDIS017, doc	
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29 IA Correspondence	30 IA Correspondence	31 IA Correspondence	31 IA Correspondence	32 IA Correspondence	33 IA Correspondence	34 IA Correspondence	35 IA Correspondence	38 IA Correspondence	37 IA Correspondence	38 IA Correspondence	38 IA Carrespondence	38 IA Correspondence	39 IA Correspondence	40 IA Correspondence	41 tA Correspondence	42 IA Correspondence	43 IA Correspondence	43 IA Correspondence
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116368 UNITED STATES	116368 UNITED STATES	116605 UNITED STATES	116837 UNITED STATES	116859 UNITED STATES	116878 UNITED STATES	116878 UNITED STATES	116878 UNITED STATES	116878 UNITED STATES	117012 UNITED STATES	11702B UNITED STATES	117848 UNITED STATES	117847 UNITED STATES	117647 UNITED STATES	118081 UNITED STATES	116064 UNITED STATES	118084 UNITED STATES	118852 UNITED STATES	119870 UNITED STATES	119249 UNITED STATES

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DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION UNITED S'PRISTIQ	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESYENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION UNITED S'PRISTIQ																
IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552							
Wyeth	Wyeth	Wyath	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Weth	Wyeth	Wyath	
FDA	FDA	Ą	FDA	FDA	ā	FDA	FDA	FDA	Ð	Ą	FDA	FDA	FDA	FDA	FDA	FDA	FDA	FDA	FDA	
0600D3-223-US			3151A1-304-US	3151A1-306-US	3151A1-308-WW				3151A1-302-WW	3151A1-303-WW	0600D3-223-US		0600D3-223-PL	3151A1-304-US	3151A1-304-US	3151A1-304-US	3151A1-304-US		3151A1-302-WW	
S.1CNSIFDAIDvs-233 SRUNDISOS4. doc	EOP2 April 10 CMC Meeting Minutes	Addition of Guayama PR and film coat										Response to FDA Comments Rec'd during Feb 04 2003 Pre- Phase 3 Mtg							S.ICNSIFDAIDvs-233 SRUND\S068.doc	
Del Subinvest	Minutes		New Protocol	New Protocol	New Protocol	8	Follow-up	ă	New Protocol	New Protocol	Change in Prot	Review/Comment	Change in Prot	Research Facil-Del	IRB - Add	Add invest	RB - Delete	š	Research Facil - Add	
Prot Amend	Meeting/Telecon	Info Amend-CMC	Prot Amend	Prot Amend	Prot Amend	Info Amend-Pharm/Tox	Safety Rpt: Clin	Info Amend-PharmTox	Prot Amend	Prot Amend	Prot Amend	Request	Prot Amend	Info Amend-Clin	Into Amend-Clin	Prot Amend	Into Amend-Clin	Info Amend-PharmTox	Into Amend-Clin	
57 IA Correspondence	58 IA Correspondence	59 IA Correspondence	60 IA Correspondence	61 IA Correspondence	62 iA Correspondence	63 IA Correspondence	64 IA Correspondence	65 IA Correspondence	68 IA Correspondence	67 IA Correspondence	68 IA Correspondence	69 IA Correspondence	70 IA Correspondence	71 IA Correspondence	71 IA Correspondence	71 IA Correspondence	71 IA Correspondence	72 IA Correspondence	73 IA Correspondence	
8-Apr-03	21-Apr-03	24-Apr-03	24-Apr-03	25-Apr-03	28-Apr-03	1-Mey-03	9-May-03	14-May-03	16-May-03	16-May-03	16-May-03	29-May-03	4-Jun-03	18-Jun-03	18-Jun-03	18-Jun-03	18-Jun-03	18-Jun-03	23-Jun-03	
119249 UNITED STATES	119759 UNITED STATES	119951 UNITED STATES	119954 UNITED STATES	119962 UNITED STATES	119977 UNITED STATES	120486 UNITED STATES	121145 UNITED STATES	121217 UNITED STATES	121466 UNITED STATES	121488 UNITED STATES	121503 UNITED STATES	122331 UNITED STATES	122425 UNITED STATES	123088 UNITED STATES	123088 UNITED STATES	123088 UNITED STATES	123088 UNITED STATES	123096 UNITED STATES	123297 UNITED STATES	

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IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 84,552	IND 64,552	IND 64,552	IND 84,552	IND 64,552	IND 84,552	IND 64,552	IND 64,552	IND 64,552				
Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyath	Wyeth	Wyeth	Wyeth	Weth	Wyeth								
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3151A1-302-WW	3151A1-302-WW			0600D3-223-US	060003-223-US		3151A1-306-US	3151A1-308-US	3151A1-308-US	3151A1-308-US	3151A1-304-US	3151A1-303-WW	3151A1-303-WW			3151A1-174-US	3151A1-302-WW		3151A1-303-WW
S.I.C.NSIFDAIDve-233 SRUNDISO68 doc	S:\CNS\FDA\D\#-233 SR\\ND\\S068 doc			Submestion provides for addition/deletion of subinvestigations for Protocol No. 060003-23-US.	didition/deletion of subinessignment and subinessignment Protocol No. 0600D3-23-US.	Rationale Designation Starting Material			S:\CNS\FDA\Dvs-233 SRUND\S077. doc	S.ICNSIFDADA-233 SRUND/S077,doc		S:\CMS\FDA\Dve.233 SR\\ND\\S078 doc	S.ICNSIFDAIDve-233 SRUNDISOT 9.doc						S I CHSFDAIDW-233 SRUNDISOBA doc
Del Subinvest	Add Invest	Īġ	ייית ניית (סי	Add Subinvest	Del Subinvent		Address Change	Add Invest	Add Subinvest	Del Subinvest	Change in Prot	Name Change	Add Invest		Лох	New Protocol	Change in Prot	Other	Add invest
Prot Amend	Prot Amend	Info Amend-Pharm/Tox	Info Amend-Pharm	Prot Amend	Prot Amend	Gen Cor	Info Amend-Clin	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Info Amend-Clin	Prot Amend	Info Amend-CMC	Info Amend-Pharm/Tox	Prot Amend	Prot Amend	Response to	Prot Amend
73 IA Correspondence	73 IA Correspondence	74 IA Correspondence	75 IA Correspondence	78 IA Correspondence	78 IA Correspondence	77 IA Correspondence	78 IA Correspondence	78 IA Correspondence	79 IA Correspondence	79 IA Correspondence	80 IA Correspondence	81 IA Correspondence	61 IA Correspondence	62 IA Correspondence	83 IA Correspondence	84 IA Correspondence	85 IA Correspondence	85 tA Correspondence	88 IA Correspondence
23-Jun-03	23-Jun-03	26~Jun-03	23-711-03	29-Jul-03	29~1/1-03	29-714-03	1-Aug-03	1-Aug-03	11-Aug-03	11-Aug-03	14-Aug-03	21-Aug-03	21-Aug-03	25-Aug-03	26-Aug-03	27-Aug-03	3-Sep-03	3-Sep-63	4-Sep-03
123297 UNITED STATES	123297 UNITED STATES	123521 UNITED STATES	125232 UNITED STATES	125577 UNITED STATES	125577 UNITED STATES	125617 UNITED STATES	125832 UNITED STATES	125832 UNITED STATES	128374 UNITED STATES	128374 UNITED STATES	126508 UNITED STATES	126875 UNITED STATES	126875 UNITED STATES	126950 UNITED STATES	126966 UNITED STATES	128987 UNITED STATES	127331 UNITED STATES	127331 UNITED STATES	127433 UNITED STATES

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IND 84,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 84,552	IND 64,552	IND 64,552	(ND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552						
Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Weth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Weth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	W.AR	
FDA	FDA	FDA	ą	FDA	F0.	FDA	FDA	FDA	FDA	FDA	FDA	FDA	FOA	FDA	FDA	FDA	P. P	Ą	
3151A1-303-WW	3151A1-306-US	3151A1-308-WW	3151A1-303-WW	0600D3-223-US	D600D3-223-US	3151A1-302-WW	3151A1-302-WW		3151A1-306-US	3151A1-306-US	3151A1-303-WW	3151A1-303-WW	3151A1-303-WW			3151A1-304-US		3151A1-308-WW	
SACNSFDADvs-233 SRUNDSD84.doc				S.ICNSFDADVS-233 SRUND\S087.doc	S.ICNSIFDAIDVS-233 SRVINDS087.doc	S.ICNSIFDAIDvs-233 SRUNDISOBS doc	S ICNS/FDAIDve-233 SRUND\SD8B.doc	Requesting a Type C Meeting with Agency	S.(CNS)FDAIDA-233 SRUND\S090.doc	S. CNSF DAUD-#-233 SRUDISSOG dec S. CNSFT DAUD-#-233	SRIVINDSRS doc Submission provides for a new investigation and the additional design of submessigation. S.NORSECALDS.	Submission provides for a new investigation and the addition/defellon of submissigations S.(CNS)/FDAUD-233 SRINID/SUBS 4.0c. SRINID/SUBS 4.0c.	Submission provides for a new investigator and the addition/detelon of subinvestigators.						
Add Subinvest	Change in Prot	Change in Prot	Change in Prot	Add Subinvest	Del Subinvest	Add Invest	Del Invest	Meeting-Request	Add Subinvest	Del Subinvest	Add invest	Del Subinvest	Add Subinvest	Follow-up	Īά	Add Subinvest	Information Request	Add invest	
Prot Amend	Prot Amend	Medting/Telecon	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Safety Rot. Clin	Info Amend-Pharm/Tox	Prot Amend	Response to	Prot Amend							
86 IA Correspondence	87 IA Correspondence	88 IA Correspondence	89 IA Correspondence	90 IA Correspondence	90 IA Correspondence	91 IA Correspondence	91 IA Correspondence	92 IA Correspondence	93 IA Correspondence	93 IA Correspondence	94 IA Correspondence	94 IA Correspondence	94 IA Correspondence	85 tA Correspondence	96 IA Correspondence	97 IA Correspondence	88 IA Correspondence	99 IA Correspondence	
4-Sep-03	5-Sap-03	S-Sep-03	8-Sep-03	B-Sep-03	9-Sep-03	8-Sep-03	9-Sep-03	11-Sep-03	11-Sep-03	11-Sep-03	11-Sep-03	11-Sep-03	11-Sep-03	16-Sep-03	23-Sep-03	29-Sep-03	29-Sep-03	24-0c1-03	
127433 UNITED STATES	127549 UNITED STATES	127550 UNITED STATES	127601 UNITED STATES	127820 UNITED STATES	127820 UNITED STATES	127638 UNITED STATES	127838 UNITED STATES	127704 UNITED STATES	127712 UNITED STATES	127712 UNITED STATES	127714 UNITED STATES	127714 UNITED STATES	127714 UNITED STATES	127847 UNITED STATES	128143 UNITED STATES	128391 UNITED STATES	128410 UNITED STATES	128413 UNITED STATES	

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UNITED S' PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S' PRISTIO	UNITED S' PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S' PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	
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IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 84,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	(ND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 84,552	IND 84,552	IND 64,552	IND 84,552	IND 64,552	
Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyath	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	
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	3151A1-302:WW		3151A1-302-WW		3151A1-308-WAV	3151A1-306-US	3151A1-308-US	3151A1-306-US	3151A1-306-US				3151A1-303-WW	3151A1-303-WW	3151A1-303-WW	3151A1-306-US	3151A1-306-US	3151A1-306-US		
										Wyeth Meeting Minutes of 11- 6-03 FDAWyeth	Wyeth Meeting Minutes of 11- 6-03 FDAWyeth	Response to Reproductive- Related Comments								
Add Invest	Add Invest	Del Invest	Del invest	Add Invest	Add Invest	Address Change	Add Subinvest	Del Subinvest	Name Change	Other	Minutes	Info Request-Respon	Add Invest	Add Subinvest	Del Subinvest	Del Invest	Del Subinvest	Add Subinvest	Review/Comment Req	
Prot Amend	Prot Amend	Prot Amend	Prat Amend	Prot Amend	Prot Amend	info Amend-Clin	Prot Amend	Prot Amend	Info Amend-Clin	CMC Issues	Meeting/Telecon	Clinical fesues	Prot Amend	Prot Amend	Response to					
100 IA Correspondence	100 IA Correspondence	100 IA Correspondence	100 IA Correspondence	101 IA Correspondence	101 IA Correspondence	102 IA Correspondence	102 IA Correspondence	102 IA Correspondence	102 IA Correspondence	103 IA Correspondence	103 IA Correspondence	104 IA Correspondence	105 IA Correspondence	105 tA Correspondence	105 IA Cenespondence	106 IA Correspondence	106 IA Correspondence	106 IA Correspondence	107 IA Correspondence	
28-Oct-03	28-Oct-03	28-Oct-03	28-0ct-03	28-0ct-03	28-0ct-03	31-0c1-03	31-0ct-03	31-0ct-03	31-0ct-03	14-Nov-03	14-Nov-03	25-Nov-03	3-Dec-03	3-Dec-03	3-Dec-03	3-Dec-03	3-Dec-03	3-Dec-03		
129556 UNITED STATES	128558 UNITED STATES	128558 UNITED STATES	129558 UNITED STATES	129560 UNITED STATES	128560 UNITED STATES	128870 UNITED STATES	129870 UNITED STATES	128870 UNITED STATES	128870 UNITED STATES	130393 UNITED STATES	130393 UNITED STATES	130928 UNITED STATES	131177 UNITED STATES	131177 UNITED STATES	131177 UNITED STATES	131185 UNITED STATES	131165 UNITED STATES	131185 UNITED STATES	131850 UNITED STATES	

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DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENIJAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENIJFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION UNITED S'PRISTIQ													
IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552													
Wyeth	Ą	Wyeth	Wyath	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth								
FDA	Wyeth	FDA	FDA	FDA	FD.	FDA	FDA	FDA	FD.	FOA	Ð	FDA								
3151A1-318-US		3151A1-318-US		3151A1-177-US	3151A1-317-US	3151A1-306-US		******				3151A1-303-WW	3151A1-303-WW	3151A1-308-US	3151A1-306-US		3151A1-31&-US	3151A1-318-US	3151A1-318-US	
			IVIVC/Comparator Info				Truintrain or re-risse 5 Meeting Request (Hypertension and Techycardia)	FDA will not need any more detailed information	3151A1-303	Request for Feedback on Mouse Carc Study Dose Adjustment	3151A1-303					3151A1-303				
New Protocol	Add invest	Add Invest		New Protocol	New Protocol	Add Subinvest		Information Request	Initial Written	Expedited Review	Follow-up	Add Subinvest	Del Subinvest	Add Subinvest	Del Subinvest	Follow-up	Add Invest	Add Subinvest	Del Subinvest	
Prot Amend	Prot Amend	Prot Amend	Info Amend-CMC	Prot Amend	Prot Amend	Prot Amend	Gen Corr	Response to	Safety Rpt. Clin	Request	Safety Rpt: Clin	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Safety Rpt: Clin	Prot Amend	Prot Amend	Prot Amend	
108 IA Correspondence	108 IA Correspondence	108 IA Correspondence	109 IA Correspondence	110 IA Correspondence	111 IA Correspondence	112 IA Correspondence	113 IA Correspondence	113 IA Correspondence	114 IA Correspondence	115 IA Correspondence	116 tA Correspondence	117 IA Correspondence	117 IA Correspondence	118 IA Correspondence	118 IA Correspondence	119 IA Correspondence	121 IA Correspondence	121 IA Correspondence	121 IA Correspondence	
22-Dec-03	22-Dec-03	22-Dec-03	15-Jan-04	15-Jan-04	21-Jan-04	21-Jan-04	27-Jan-04	31-Mar-04	4-Fab-04	13-Fab-04	18-Feb-04	19-Feb-04	19-Feb-04	20-Feb-04	20-Feb-04	23-Feb-04	3-Mar-04	3-Mar-04	3-Mar-04	
131890 UNITED STATES	131990 UNITED STATES	131890 UNITED STATES	132814 UNITED STATES	132848 UNITED STATES	133048 UNITED STATES	133084 UNITED STATES	133245 UNITED STATES	135809 UNITED STATES	133539 UNITED STATES	133974 UNITED STATES	134155 UNITED STATES	134201 UNITED STATES	134201 UNITED STATES	134247 UNITED STATES	134247 UNITED STATES	134356 UNITED STATES	134815 UNITED STATES	134815 UNITED STATES	134815 UNITED STATES	

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UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S' PRISTIQ	UNITED S' PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S' PRISTIQ	UNITED S' PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S' PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S' PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ
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IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 84,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552					
Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth
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3151A1-309-EU	3151A1-303-WW	3151A1-303-WW	3151A1-303-WW	3151A1-304-US	3151A1-304-US	3151A1-304-US	3151A1-306-US	3151A1-306-US	3151A1-302-WW	3151A1-302-WW	3151A1-302-WW	3151A1-303-WW	3151A1-317-US		3151A1-318-US			3151A1-309-EU	
																3151A1-303			
New Pratocol	Add Invest	Del Subinvest	Add Subinvest	Add Subinvest	Ogper	Del Subinvest	Add Subinvest	Del Subinvest	Address Change	Add Subinvest	Other	Change in Prot	Add Invest	ă	Del Subinvest	Follow-up	Subm	Add Invest	Initial Written
Prot Amend	Prot Amend	Prot Amend	Prot Amend	Info Amend-Clin	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Info Amend-Pharm/Tox	Prot Amend	Safety Rpt: Clin	Annual Report-IDA	Prot Amend	Safety Rpt: Clin					
122 IA Correspondence	123 IA Correspondence	123 IA Correspondence	123 IA Correspondence	124 IA Correspondence	124 IA Correspondence	124 IA Correspondence	125 IA Correspondence	125 IA Correspondence	126 IA Correspondence	126 IA Correspondence	128 iA Correspondence	127 IA Cerrespondence	128 IA Correspondence	129 IA Correspondence	130 IA Correspondence	131 IA Correspondence	132 IA Correspondence	133 IA Correspondence	134 IA Carrespondence
22-Mar-04	24-Mar-04	24-Mar-04	24-Mar-04	30-Mar-04	30-Mar-04	30-Mar-04	31-Mar-04	31-Mar-04	31-Mar-04	31-Mar-04	31-Mar-04	31-Mar-04	7-Apr-04	8-Apr-04	9-Apr-04	12-Apr-04	21-401-04	22-Apr-04	27-Apr-04
135626 UNITED STATES	135568 UNITED STATES	135568 UNITED STATES	135568 UNITED STATES	135686 UNITED STATES	135888 UNITED STATES	135686 UNITED STATES	135722 UNITED STATES	135722 UNITED STATES	135725 UNITED STATES	135725 UNITED STATES	135725 UNITED STATES	135727 UNITED STATES	135919 UNITED STATES	138035 UNITED STATES	136084 UNITED STATES	136122 UNITED STATES	138478 UNITED STATES	136516 UNITED STATES	136702 UNITED STATES

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	DESVENLAFAXINE SUCCINATE (DVS-23) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-223) FOR THE TREATMENT OF DEPRESSION UNITED S'PRISTIQ														
	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	(ND 64,552	IND 64,552	IND 64,552	IND 64,552
	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth
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	3151A1-303-WW	3151A1-303-WW	3151A1-303-WW	3151A1-303-WW		3151A1-304-US	3151A1-306-US	3151A1-306-US	3151A1-317-US	3151A1-317-US	3151A1-317-US	3151A1-320-US	3151A1-320-US	3151A1-31B-US	3151A1-318-US					
IND Activities					RPT Update	Addition of a subinvestigator														Copy of submission sent on 5/28 (SN 144).
	Add Invest	Office	Del Subinvest	Add Subinvest		Add Subinvest	Add Subinvest	Dei Subinvest	Add Invest	Del Subinvest	Add Subinvest	New Protocol	Add Invest	Add Subinvest	Del Subinvest	Initial Written	Initial Written	Review/Comment	Other	Other
	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Info Amend-CMC	Prot Amend	Safety Rpt. Clin	Safety Rpt: Clin	Request	Protocol-Clinical	Protocol-Clinical									
	135 IA Correspondence	135 IA Correspondence	135 IA Correspondence	135 IA Correspondence	136 IA Correspondence	137 IA Correspondence	138 tA Correspondence	138 IA Correspondence	139 IA Correspondence	139 IA Correspondence	139 IA Correspondence	140 IA Correspondence	140 IA Correspondence	141 IA Correspondence	141 IA Correspondence	142 IA Correspondence	143 IA Correspondence	144 IA Correspondence	144 IA Correspondence	144 IA Correspondence
	30-Apr-04	30-Apr-04	30-Apr-04	30-Apr-04	10-May-04	13-May-04	13-May-04	13-May-04	14-May-04	14-May-04	14-May-04	18-May-04	18-May-04	18-May-04	18-May-04	28-May-04	28-May-04	28-May-04	, 28-May-04	2-Jun-04
	138800 UNITED STATES	136800 UNITED STATES	136800 UNITED STATES	136800 UNITED STATES	137183 UNITED STATES	137370 UNITED STATES	137372 UNITED STATES	137372 UNITED STATES	137382 UNITED STATES	137362 UNITED STATES	137382 UNITED STATES	137467 UNITED STATES	137467 UNITED STATES	137475 UNITED STATES	137475 UNITED STATES	137842 UNITED STATES	137859 UNITED STATES	137939 UNITED STATES	137839 UNITED STATES	136060 UNITED STATES

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IND 64,552	IND 84,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 84,552	IND 64,552	IND 64,552							
Wyeth	Wyeth	Wyath	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyath	Wyeth	Wyeth	Wyeth	Weth	Wyeth	Wyeth	Wyeth	Wyeth	
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			3151A1-303-WW	3151A1-303-WW	3151A1-303-WW	3151A1-303-WW	3151A1-303-WW		3151A1-309-EU	3151A1-306-US	3151A1-306-US	3151A1-304-US	3151A1-304-US	3151A1-318-US	3151A1-180-US					
	9 month Toxicity Study in Dogs.															į	Request FUA feedback regarding the proposed specific analyses of the DESS data.			
Follow-up	Info Req-Response	Initial Written	Research Facil - Add	Add Invest	Add Subinvest	Address Change	Del Subinvest	Initial Written	Add Invest	Add Subinvest	Del Subinvest	Address Change	Del Subinvest	Add Subinvest	New Protocol	- Follow-up	Review/Comment	Follow-up	Initial Written	
Safety Rpt. Clin	Non-Cinical Issues	Safety Rpt: Clin	Info Amend-Clin	Prot Amend	Prot Amend	Info Amend-Clin	Prot Amend	Safety Rpt: Clin	Prot Amend	Prot Amend	Prot Amend	Info Amend-Clin	Prot Amend	Prot Amend	Prot Amend	Safety Rpt: Clin	Request	Safety Rpt: Clin	Safety Rpt. Clin	
145 IA Correspondence	146 IA Correspondence	147 IA Correspondence	148 IA Correspondence	149 IA Conespondence	150 IA Correspondence	151 IA Correspondence	151 IA Correspondence	152 IA Correspondence	152 IA Correspondence	153 IA Correspondence	154 IA Correspondence	155 IA Correspondence	157 IA Correspondence	158 IA Correspondence	159 IA Correspondence					
2-Jun-04	2-Jun-04	3-Jun-04	3-hun-04	3-Jun-64	3-Jun-04	3-Jun-04	3-Jun-04	4-Jun-04	7-Jun-04	14-Jun-04	14-Jun-04	14-tim-04	14-lun-04	14-Jun-04	14-Jun-04	15-Jun-04	17-Jun-04	17-Jun-04	18-Jun-04	
137998 UNITED STATES	138020 UNITED STATES	138068 UNITED STATES	138080 UNITED STATES	138080 UNITED STATES	136080 UNITED STATES	136080 UNITED STATES	136080 UNITED STATES	130100 UNITED STATES	138123 UNITED STATES	138421 UNITED STATES	138421 UNITED STATES	138423 UNITED STATES	138423 UNITED STATES	138425 UNITED STATES	138443 UNITED STATES	138472 UNITED STATES	138567 UNITED STATES	138578 UNITED STATES	138601 UNITED STATES	

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3151A1-304-US	3151A1-181-US	3151A1-308-WW		3151A1-303-WW	3151A1-303-WW	3151A1-303-WW		3151A1-306-US	3151A1-306-US	3151A1-304-US	3151A1-304-US	3151A1-304-US		3151A1-304-US		3151A1-320-US	3151A1-320-US	3151A1-309-EU	3151A1-303-WW
			9				update to Dra Co. In LC analytical method for DS punty, stability data for DP & DS								tsenb				
Change in Prot	New Protocol	Change in Prot	Int With ollow-up	Add Invest	Del Subinvest	Add Subinvest		Add Subinvest	Del Subinvest	Address Change	Add Subinvest	Del Subinvest	Follow-up	Change in Prol	Information Request	Add Invest	Add Subinvest	Add Invest	Add Subinvest
Prot Amend	Prot Amend	Prot Amend	Safety Rpt: Clin	Prot Amend	Prot Amend	Prot Amend	Info Amend-CMC	Prot Amend	Prot Amend	Info Amend-Clin	Prot Amend	Prot Amend	Safety Rpt. Clin	Prot Amend	Response to	Prot Amend	Prot Amend	Prot Amend	Prot Amend
160 IA Correspondence	161 IA Correspondence	162 IA Correspondence	163 IA Correspondence	164 IA Correspondence	164 IA Correspondence	164 IA Correspondence	165 IA Correspondence	168 tA Correspondence	166 IA Correspondence	167 IA Correspondence	167 IA Correspondence	167 tA Correspondence	168 IA Correspondence	169 IA Correspondence	169 IA Correspondence	170 IA Correspondence	170 IA Correspondence	171 IA Correspondence	172 IA Correspondence
21-Jun-04	24-Jun-04	24-Jun-04	28-Jun-04	30-Jun-04	30-Jun-04	30-Jun-04	30-Jun-04	13000	1-36-04	2-Jul-04	2-Jul-04	2-74-04	20-Jul-04	21-Jul-04	21-34-04	30-141-04	30-344-04	2-Aug-04	2.Aug-04
138847 UNITED STATES	138717 UNITED STATES	138767 UNITED STATES	13886 UNITED STATES	138987 UNITED STATES	138967 UNITED STATES	138967 UNITED STATES	138969 UNITED STATES	139026 UNITED STATES	138026 UNITED STATES	139082 UNITED STATES	139082 UNITED STATES	139082 UNITED STATES	139527 UNITED STATES	139569 UNITED STATES	139569 UNITED STATES	138841 UNITED STATES	138841 UNITED STATES	138653 UNITED STATES	139890 UNITED STATES

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	3151A1-303-WW	3151A1-303-WW	3151A1-317-US	3151A1-306-US	3151A1-306-US		3151A1-307-US		3151A1-320-US	3151A1-320-US	3151A1-308-WW	3151A1-303-WWV	3151A1-303-WW	3151A1-303-WW	3151A1-308-US	3151A1-306-US	3151A1-303-WW	3151A1-303-WW	3151A1-303-WW
IND Activities					3151A1-307-US A 6-Month.	Long-Term Safety of DVS-233 St in Floten Outbasents With Mapo Depressive Desorder 3151A1-307-JSA 6-Month Open-Label Evaluation of the	Long- term Safety of UVS-253 SR in Elderly Outpatents With Major Depressive Disorder												
	Odber	Del Subinvest	Add Subinvest	Add Subinvest	Dei Subinvest	New Protocol	New Protocol	Initial Written	Add Subinvest	Del Subinvest	Add Invest	Add invest	Del Invest	Add Subinvest	Add Subinvest	Det Subinvest	Address Change	Del Subinvest	Add Subinvest
	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Safety Rpt. Clin	Prot Amend	Info Amend-Clin	Prot Amend	Prot Amend							
	172 IA Correspondence	172 IA Correspondence	173 IA Correspondence	174 IA Correspondence	174 IA Correspondence	175 IA Correspondence	175 IA Correspondence	176 IA Correspondence	177 IA Correspondence	177 IA Correspondence	178 IA Correspondence	178 IA Correspondence	178 IA Correspondence	178 IA Correspondence	179 IA Correspondence	179 IA Correspondence	180 IA Correspondence	180 IA Correspondence	150 IA Correspondence
	2-Aug-04	2-Aug-04	4-Aug-04	4-Aug-04	4-Aug-04	10-Aug-04	10-Aug-04	20-Aug-04	31-Aug-04	31-Aug-04	31-Aug-04	31-Aug-04	31-Aug-04	31-Aug-04	1-Sep-04	1-Sep-04	1-Sep-04	1-Sep-04	1-Sep-04
	139690 UNITED STATES	139890 UNITED STATES	139967 UNITED STATES	138989 UNITED STATES	138969 UNITED STATES	140265 UNITED STATES	140285 UNITED STATES	140847 UNITED STATES	141197 UNITED STATES	141197 UNITED STATES	14119B UNITED STATES	141198 UNITED STATES	141198 UNITED STATES	141198 UNITED STATES	141238 UNITED STATES	141238 UNITED STATES	141243 UNITED STATES	141243 UNITED STATES	141243 UNITED STATES

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IND 64.552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 84,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552
Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyath	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth
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Add Subinves	Del Subinvest	Follow-up	Follow-up	Address	Add Invest	Del Subinves	Add Subinves	Name Change	Change in Prot	Add Invest	Add Subinves	Initial Written	Add Invest	Add invest	Del Subinvesi	Add IRB	Add Re	Del Subinvest	Add Subinvest
Prot Amend	Prot Amend	Safety Rpt: Clin	Safety Rpt: Clin	Info Amend-Clin	Prot Amend	Prot Amend	Prot Amend	Info Amend-Clin	Prot Amend	Prot Amend	Prot Amend	Safety Rpt. Clin	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend
181 IA Carrespondence	181 IA Correspondence	182 IA Correspondence	183 IA Correspondence	184 IA Correspondence	184 iA Correspondence	184 IA Correspondence	184 IA Correspondence	184 IA Correspondence	185 IA Correspondence	188 IA Correspondence	188 IA Correspondence	187 IA Correspondence	188 IA Correspondence	159 IA Correspondence	169 IA Correspondence	189 !A Carrespondence	189 IA Correspondence	18B IA Correspondence	189 (A Correspondence
2-Sep-04	2-Sep-04	2-Sep-04	3-Sep-04	8-Sep-O4	9-Sep-04	9-Sep-04	9-Sep-04	9-Sep-04	16-Sep-04	17-Sep-04	17-Sep-04	22-Sep-04	27-Sep-04	29-Sep-04	29-Sep-04	29-Sep-04	29-Sep-04	29-Sep-04	29-Sep-04
141258 UNITED STATES	141256 UNITED STATES	141278 UNITED STATES	141330 UNITED STATES	141390 UNITED STATES	141390 UNITED STATES	141390 UNITED STATES	141390 UNITED STATES	141390 UNITED STATES	141830 UNITED STATES	141697 UNITED STATES	141897 UNITED STATES	142116 UNITED STATES	142334 UNITED STATES	142509 UNITED STATES	142509 UNITED STATES	142509 UNITED STATES	142509 UNITED STATES	142509 UNITED STATES	142509 UNITED STATES

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3151A1-318-US		3151A1-320-US	3151A1-320-US	3151A1-320-US	3151A1-320-US	3151A1-306-US	3151A1-306-US	3151A1-320-US			3151A1-307-US	3151A1-307-US	3151A1-307-US	3151A1-318-US	3151A1-303-WW	3151A1-307-US	3151A1-303-WW	3151A1-303-WW	3151A1-318-US
Add Submest	in Follow-up	Add invest	Del Subinvest	Add IRB	Add Research Facil	Del Subinvest	Add Subinvest	Add Subinvest	lin Follow-up	lin Inde Witten	Add invest	Add Subinvest	Add Resserch Facil	Del Submyest	Del Subinvest	AddIRB	Add Subinvest	Address Change	Add Submyest
Prot Amend	Safety Rpt. Clin	Prot Amend	Safety Rpt. Clin	Safety Rpt: Clin	Prot Amend	Prot Amend	Prof Amend	Prof Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend						
189 IA Correspondence	190 IA Correspondence	191 IA Correspondence	191 iA Correspondance	191 IA Correspondence	192 IA Correspondence	193 IA Correspondence	194 IA Correspondence	194 IA Correspondence	194 IA Correspondence	194 IA Correspondence	194 IA Correspondence	194 IA Correspondence	194 IA Correspondence	184 IA Correspondence	194 IA Correspondence				
29-Sep-04	30-Sep-04	6-Oct-04	6-04-04	6-Oct-04	8-Oct-04	6-Oct-04	6-Oct-04	6-Oct-04	12.0ct-04	18-Oct-04	20-Oct-04	20-051-04	20-Oct-04	20-0ct-04	20-051-04	20-Oct-04	20-0:1-04	20-001-04	20-0ct-04
142509 UNITED STATES	142570 UNITED STATES	142908 UNITED STATES	142908 UNITED STATES	142908 UNITED STATES	142808 UNITED STATES	142908 UNITED STATES	142908 UNITED STATES	142906 UNITED STATES	14314D UNITED STATES	143433 UNITED STATES	143543 UNITED STATES	143543 UNITED STATES	143543 UNITED STATES	143543 UNITED STATES	143543 UNITED STATES	143543 UNITED STATES	143543 UNITED STATES	143543 UNITED STATES	143543 UNITED STATES

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Wyeth	Wyath	Wyath	Weth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth						
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		Type A meeting request for 150 mg					CMC. Intomason to support manufacturing equipment change; Aveiox as a positive control												
Follow-up	Follow-up	Meeting-Request	Initial Written	ĕ	Intal Written	Change in Prot		Follow-up	Add Invest	Add Subinvest	Add Invest	Add Subinvest	Add Subinvest	Del Subinvest	Dei Subinvest	Name Change	Add IRB	Add IRB	Add Research Facil
Safety Rpt. Clin	Safety Rpt: Clin	Meeting/Telecon	Safety Rpt: Clin	Info Amend-Pharm/Tox	Safety Rpt. Clin	Prot Amend	Info Amend-CMC	Safety Rpt: Clin	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend
195 IA Correspondence	196 IA Correspondence	197 IA Correspondence	198 IA Correspondence	199 IA Correspondence	200 IA Correspondence	201 (A Correspondence	202 IA Carrespondence	203 IA Correspondence	204 IA Correspondence	204 IA Correspondence	204 IA Correspondence	204 IA Correspondence	204 IA Correspondence	204 IA Correspondence	204 IA Correspondence	204 IA Correspondence	204 IA Correspondence	204 IA Correspondence	204 IA Correspondence
20-0ct-04	29-0c1-04	10-Nov-04	2-Nov-04	9-Nov-04	10-Nov-04	10-Nov-04	11-Nov-04	15-Nov-04	19-Nov-04	19-Nov-04	19-Nov-04	19-Nov-04	19-Nov-04	19-Nov-04	19-Nov-04	18-Nov-04	19-Nov-04	19-Nov-04	19-Nov-04
143573 UNITED STATES	144040 UNITED STATES	144241 UNITED STATES	144253 UNITED STATES	144852 UNITED STATES	144722 UNITED STATES	144739 UNITED STATES	144848 UNITED STATES	144948 UNITED STATES	145272 UNITED STATÉS	145272 UNITED STATES	145272 UNITED STATES	145272 UNITED STATES	145272 UNITED STATES	145272 UNITED STATES	145272 UNITED STATES	145272 UNITED STATES	145272 UNITED STATES	145272 UNITED STATES	145272 UNITED STATES

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IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64.552	IND 64,552	IND 64,552
Wyeth	Weth	Wyed	Wyeth	Wyeth	Weth	wyeth	Weth	Weth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth
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3151A1-303-WW	3151A1-306-US	3151A1-318-US	3151A1-303-WW	3151A1-307-US								3151A1-309-EU	3151A1-309-EU	3151A1-309-EU	3151A1-318-US	3151A1-303-WW	3151A1-309-EU	3151A1-303-WW	3151A1-303-WW
Add Research Facil	Address Change	Dei Subinvest	Del Subinvest	Add Subinvest	n Follow-up	n init Witt Follow-up	אניות ל סא	Information Request	n Folow-up	n Inti Write ollow-up	п Гейем-цр	Add invest	Add IRB	Add Research Facil	Name Change	Address Change	Add Subinvest	Del Subinvest	Add Subinvest
Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Safety Rpt. Clin	Safety Rpt: Clin	Info Amend-PharmTox	Response to	Safety Rpt: Clin	Safety Rpt: Clin	Safety Rpt: Clin	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prof Amend	Prot Amend	Prot Amend	Prot Amend
204 IA Correspondence	204 IA Correspondence	204 IA Correspondence	204 1A Correspondence	204 IA Correspondence	205 1A Correspondence	206 1A Correspondence	207 IA Correspondence	208 IA Correspondence	209 IA Correspondence	210 IA Correspondence	211 IA Correspondence	212 IA Correspondence	212 IA Correspondence	212 IA Correspondence	212 IA Correspondence	212 IA Correspondence	212 IA Carrespondence	212 IA Correspondence	212 IA Carrespondence
19-Nov-04	19-Nov-04	19-Nov-04	19-Nov-04	19-Nov-04	19-Nov-04	22-Nov-04	22-Nov-04	23-Nov-04	1-Dec-04	6-Dec-04	20-Dec-04	20-Dec-04	20-Dec-04	20-Dec-04	20-Dec-04	20-Dec-04	20-Dec-04	20-Dec-04	20-Dec-04
145272 UNITED STATES	145272 UNITED STATES	145272 UNITED STATES	145272 UNITED STATES	145272 UNITED STATES	145274 UNITED STATES	145325 UNITED STATES	145348 UNITED STATES	145428 UNITED STATES	145713 UNITED STATES	146010 UNITED STATES	146888 UNITED STATES	146824 UNITED STATES	146924 UNITED STATES	146924 UNITED STATES	148924 UNITED STATES	146924 UNITED STATES	146924 UNITED STATES	146924 UNITED STATES	146924 UNITED STATES

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Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyath	Wyeth	Wyath	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyath	Wyeth	wyed	Wyeth	Wyeth	Wyeth	Wyeth	
FDA	FDA	FDA	FDA	FDA	PP	FDA	Ą	ą	FDA	Ð	FDA	Ą	Ş	Ą	FDA	Ą	FDA	ą	FDA	
3151A1-316-US					3151A1-193-US		3151A1-183-US			3151A1-184EU			3151A1-302-WW	3151A1-303-WW	3151A1-320-US	WW-505-14151E	315141-3174/5	3151A1-303-WW	3151A1-302-WW	
Del Subinvest	Follow-up	Follow-up	Foltow-up	New Protocol	New Protocol	New Protocol	New Protocol	Change in Prot	New Protocol	New Protocol	Change in Prot	Change in Prot	Add Invest	Add Subinvest	Add Subinvest	Del Subinvest	Name Change	Name Change	Name Change	
Prot Amend	Safety Rpt Clin	Safety Rpt: Clin	Safety Rpt. Clin	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	
212 IA Correspondence	213 IA Correspondence	214 IA Correspondence	215 IA Correspondence	216 IA Correspondence	216 IA Correspondence	217 IA Correspondence	217 IA Correspondence	218 IA Correspondence	219 IA Correspondence	219 IA Correspondence	220 IA Correspondence	221 IA Correspondence	222 IA Correspondence	222 IA Correspondence	222 IA Correspondence	222 1A Correspondence	222 IA Correspondence	222 IA Correspondence	222 lA Correspondence	
20-Dec-04	22-Dec-04	23-Dec-04	29-Dec-04	7-Jan-05	7-Jan-05	11-Jan-05	11-Jan-05	11-Jan-05	14-Jan-05	14-Jan-05	17-Jan-05	19-Jan-05	18-Jan-05	18-Jan-05	19-Jan-05	19-Jan-05	19-Jan-05	19-Jan-05	19-Jen-05	
148924 UNITED STATES	147028 UNITED STATES	147168 UNITED STATES	147291 UNITED STATES	147707 UNITED STATES	147707 UNITED STATES	147797 UNITED STATES	147787 UNITED STATES	147844 UNITED STATES	148017 UNITED STATES	146017 UNITED STATES	148104 UNITED STATES	148217 UNITED STATES	148282 UNITED STATES	148262 UNITED STATES						

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IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 84,552	IND 64,552	IND 64,552	IND 84,552						
Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyath	A Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	A Wyeth	A Wyeth	4 Wyeth	A Wyeth	A Wyeth	A Wyeth	A Wyeth	
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3151A1-317-US	3151A1-303-WW	3151A1-302-WW	3151A1-320-US	3151A1-317-US	3151A1-306-US	3151A1-317-US	3151A1-302-WW	3151A1-317-US	3151A1-302-WW	3151A1-303-WW					3151A1-195-US					
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222 IA Carrespondence	222 IA Correspondence	222 IA Correspondence	222 IA Correspondence	222 IA Correspondence	222 IA Correspondence	222 lA Correspondence	223 IA Correspondence	224 IA Correspondence	225 IA Correspondence	226 IA Correspondence	226 IA Correspondence	227 IA Correspondence	228 IA Correspondence	229 IA Correspondence	230 IA Correspondence					
19-Jan-05	19-Jen-05	19-Jan-05	19-Jan-05	19-Jan-05	18-Jan-05	19-Jan-05	19-Jan-05	18-Jan-05	18-Jan-05	18-Jan-05	20-Jan-05	24-Jan-05	28-Jan-05	1-Feb-05	1-Feb-05	7.Feb-05	10-Feb-05	11-Feb-05	15-Feb-05	
TED STATE	TED STATE	146262 UNITED STATES	146262 UNITED STATES	TED STATE	TED STATE	148282 UNITED STATES	TED STATE	148262 UNITED STATES	148282 UNITED STATES	148282 UNITED STATES	TED STATE	148413 UNITED STATES	148698 UNITED STATES	148901 UNITED STATES	148901 UNITED STATES	149144 UNITED STATES	149388 UNITED STATES	TED STATE	149611 UNITED STATES	
148282 UNITED STATES	148262 UNITED STATES	148282 UNI	146282 UNI	148282 UNITED STATES	148282 UNITED STATES	148282 UNI	148262 UNITED STATES	148262 UNI	148262 UNI	148282 UNI	148302 UNITED STATES	148413 UNE	148698 UNI	148901 UNI	146901 UN	149144 UNI	149388 UNI	149440 UNITED STATES	149611 UNI	

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Add invest	Dai Invest	Address Change	Del Subinvest	Det Subinvest	Del Subinvest	Add Subincest	Add Subinvest	Add Subinvest	Add Subinvest	Add Subinrest	Add IRB	Add Reserch Faci	Address Charge	Del Invest	Add invest	Del Invest	Add invest	n Follow-up	n 7-Day P/F & Initial
Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Safety Rpt: Clin	Safety Rpt. Clin								
231 IA Correspondence	231 tA Correspondence	231 IA Correspondence	231 IA Correspondence	231 IA Correspondence	231 IA Correspondence	231 IA Correspondence	231 IA Correspondence	231 IA Correspondence	231 IA Correspondence	231 IA Correspondence	231 IA Correspondence	232 lA Correspondence	233 IA Carrespondence						
18-Feb-05	16-Feb-05	18-Feb-05	18-Feb-05	18-Feb-05	18-Feb-05	18-Feb-05	18-Feb-05	18-Feb-05	18-Feb-05	18-Feb-05	18-Feb-05	22-Feb-05	23-Feb-05						
149809 UNITED STATES	149809 UNITED STATES	149809 UNITED STATES	149809 UNITED STATES	149609 UNITED STATES	149809 UNITED STATES	149809 UNITED STATES	149609 UNITED STATES	149809 UNITED STATES	148809 UNITED STATES	149809 UNITED STATES	149809 UNITED STATES	148609 UNITED STATES	149809 UNITED STATES	149809 UNITED STATES	149809 UNITED STATES	149809 UNITED STATES	149809 UNITED STATES	149937 UNITED STATES	150058 UNITED STATES

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							3151A1-303-WW	3151A1-303-WW	3151A1-302-WW	3151A1-318-US	3151A1-303-WW	3151A1-318-US	3151A1-303-WW	3151A1-303-WW	S0-523-03	3151A1-303-WW	3151A1-320-US	3151A1-318-US	3151A1-320-US
				FDA email correspondence regarding biowaiver															
7-Day P/F & Initial	Follow-up	Follow-up	Follow-up		Follow-up	Follow-up	Add invest	Del Subinvest	Add Subinvest	Del Subinvest	Address Change	Address Change	Name Change	Add Research Facil	Add Subinvest	Add IRB	Add Research Facil	Add Research Facil	Nатие С hange
Safety Rpt Clin	Safety Rpt: Clin	Safety Rpt. Clin	Safety Rpt: Clin	Info Amend-CMC	Safety Rpt Clin	Safety Rpt. Clin	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend					
233 IA Correspondence	234 iA Correspondence	235 IA Correspondence	238 IA Correspondence	237 IA Carrespondence	238 IA Correspondence	239 IA Correspondence	240 IA Correspondence	240 IA Correspondence	240 IA Correspondence	240 IA Correspondence	240 IA Correspondence	240 iA Correspondence	240 IA Correspondence						
23-Feb-05	24-Feb-05	25-Feb-05	2-Mar-05	3-Mar-05	10-Mar-05	18-Mar-05	18-Mar-05	18-Mar-05	18-Mar-05	18-Mar-05	18-Mar-05	18-Mar-05	18-Mar-05						
150187 UNITED STATES	150191 UNITED STATES	150327 UNITED STATES	150529 UNITED STATES	150555 UNITED STATES	151031 UNITED STATES	151509 UNITED STATES	151514 UNITED STATES	151514 UNITED STATES	151514 UNITED STATES	151514 UNITED STATES	151514 UNITED STATES	151514 UNITED STATES	151514 UNITED STATES						

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DESVENLAFAXINE SUCCINATE (DVS.233) FOR THE TREATMENT OF DEPRESSION UNITED S'PRISTIQ	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION UNITED S'PRISTIQ														
IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552
Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth
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3151A1-320-US	3151A1-317-US	3151A1-320-US	3151A1-309-EU									3151A1-303-WW	3151A1-303-WW	3151A1-303-WW	3151A1-317-US	3151A1-318-US	3151A1-304-US		
Address Change	Addless Change	Del Subinvest	Change in Prot	Review/Comment	υΤοκ	Ройои-цр	יורסא	Fойом-цр	Initial Written	Information Request	ini Writi Follow-up	Add Subinvest	Del Subinvest	Address Change	Del Subinvest	Del Subinvest	Add Subinvest	Indea Veritien	Initial Varition
Prot Amend	Prot Amend	Prot Amend	Prof Amend	Request	Info Amend-Pharm/Tox	Safety Rpt: Clin	info Amend-Pharm√Tox	Safety Rpt Clin	Safety Rpt. Clin	Response to	Safety Rpt Clin	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Safety Rpt Clin	Safety Rpt Clin
240 IA Correspondence	240 IA Correspondence	240 IA Correspondence	241 IA Correspondence	242 IA Correspondence	243 IA Correspondence	244 IA Correspondence	245 IA Correspondence	246 IA Correspondence	247 IA Correspondence	248 IA Correspondence	249 IA Correspondence	250 IA Correspondence	250 IA Correspondence	251 IA Correspondence	252 IA Correspondence				
18-Mar-05	18-Mar-05	18-Mar-05	18-Mar-05	21-Mar-05	21-Mar-05	23-Mar-05	5-Apr-05	5-Apr-05	8-Apr-05	14-Apr-05	15-Apr-05	18-Apr-05	18-Apr-05	18-Apr-05	18-Apr-05	18-Apr-05	18-Apr-05	21-Apr-05	2-May-05
151514 UNITED STATES	151514 UNITED STATES	151514 UNITED STATES	151525 UNITED STATES	151553 UNITED STATES	151586 UNITED STATES	151742 UNITED STATES	152472 UNITED STATES	152473 UNITED STATES	152541 UNITED STATES	153076 UNITED STATES	153137 UNITED STATES	153240 UNITED STATES	153240 UNITED STATES	153536 UNITED STATES	154192 UNITED STATES				

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UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S' PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S' PRISTIQ						
DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-223) FOR THE TREATMENT OF DEPRESSION UNITED S PRISTIQ												
IND 84,552	IND 64,552	IND 64,552	IND 64,552	IND 84,552	IND 64,552	IND 64,552	IND 84,552												
Wyeth	Wyeth	Wyeth	Wyeth	Web	Wyeth	Wyeth	weth	Wyeth	Wyeth	Wyath	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth
FDA	FDA	FDA	FDA	FDA	FDA	ą	FDA	FDA	FOA	FDA	ş	Ą	FDA	FDA	FDA	FDA	Ą	FDA	FD.
			3151A1-318-US	3151A1-317-US		3151A1-303-WW	3151A1-320-US	3151A1-318-US	3151A1-317-US	3151A1-309-EU	3151A1-303-WW	3151A1-302-WW	060003-223-US	3151A1-320-US	3151A1-318-US	3151A1-320-US	3151A1-303-WW	3151A1-320-US	3151A1-303-WW
Follow-up	mTox	Inti Wents ollow-up	Change in Prot	Charge in Prot	Ройом-цр	Del invest	Del Submyest	Del Submyest	Del Subinvest	Del Submyest	Del Submest	Del Subinvest	Del Subinvest	Add Subinvest	Add Subinvest	DelRB	DeliRB	Add IRB	Add IRB
Safety Rpt: Clin	Info Amend-PharmTox	Safety Rpt Clin	Prot Amend	Prot Amend	Safety Rpt Clin	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend							
253 IA Correspondence	254 IA Correspondence	255 IA Correspondence	258 IA Correspondence	257 IA Correspondence	258 IA Correspondence	259 IA Correspondence	259 IA Correspondence	259 IA Correspondence	259 IA Correspondence	259 IA Correspondence	259 IA Correspondence								
2-May-05	3-May-05	10-May-05	12-May-05	12-May-05	16-May-05	18-May-05	16-May-05	18-May-05	18-May-05	18-May-05	18-May-05	18-May-05	18-May-05						
154200 UNITED STATES	154283 UNITED STATES	154683 UNITED STATES	154825 UNITED STATES	154843 UNITED STATES	154878 UNITED STATES	155092 UNITED STATES	155092 UNITED STATES	155092 UNITED STATES	155062 UNITED STATES	155092 UNITED STATES	155082 UNITED STATES	155092 UNITED STATES	155092 UNITED STATES	155092 UNITED STATES	155092 UNITED STATES	155082 UNITED STATES	155082 UNITED STATES	155092 UNITED STATES	155082 UNITED STATES

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DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION UNITED S'PRISTIO																	
IND 64,552	IND 64,552	IND 64,552																	
Wyeth	Weth	Wyath	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Weth	Wyed	Wyeth									
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3151A1-318-US	3151A1-303-WW	3151A1-302-WW	3151A1-303-WW	0600D3-223-PL	3151A1-309-EU						3151A1-318-US	3151A1-302-WW	3151A1-307-US	3151A1-303-WW	3151A1-320-US	3151A1-309-EU	3151A1-307-US	3151A1-303-WW	3151A1-302-WW
							Meeting/Telecon 15-JUN-05.												
Name Changs	Address Change	Add Subinvest	Add Subinvest	Add Subinvest	Add Subinvest	Follow-up	lnfo	Initial Written	Initial Written	Follow-up	Del Invest	Del Research Facil	Address Change	Address Change	Del Subinvest	Del Subinvest	Del Subinvest	Del Subinvest	Del Subinvest
Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prat Amend	Prot Amend	Safety Rpt. Clin	Mesting/Telecon	Safety Rpt' Clin	Safety Rpt: Clin	Safety Rpt: Clin	Prot Amend	Prot Amend	Prot Amend						
259 IA Correspondence	260 IA Correspondence	261 IA Correspondence	262 IA Correspondence	263 IA Correspondence	284 IA Correspondence	265 IA Correspondence	265 IA Correspondence	265 IA Correspondence	265 IA Correspondence	285 IA Correspondence	265 IA Correspondence	265 IA Correspondence	265 IA Correspondence	265 IA Correspondence					
18-May-05	18-May-05	18-May-05	18-May-05	18-May-05	18-May-05	19-May-05	27-May-05	8-Jun-05	9-Jun-05	15-Jun-05	16-Jun-05	16-Jun-05	16-Jun-05	16-Jun-05	18-Jun-05	18-Jun-05	16-Jun-05	16-Jun-05	16-Jun-05
155092 UNITED STATES	155082 UNITED STATES	155092 UNITED STATES	155092 UNITED STATES	155092 UNITED STATES	155092 UNITED STATES	155180 UNITED STATES	158114 UNITED STATES	158379 UNITED STATES	156384 UNITED STATES	156783 UNITED STATES	156892 UNITED STATES	156892 UNITED STATES							

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IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	
Weth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyath	Weth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	
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3151A1-303-WW	3151A1-307-US	3151A1-302-WW	3151A1-320-US	3151A1-302-WW	3151A1-302-WW	3151A1-302-VAV			3151A1-302-WW	3151A1-302-WW	3151A1-306-US	3151A1-302-WW	3151A1-320-US	3151A1-317-US	3151A1-317-US	3151A1-302-WW	3151A1-302-WW	3151A1-320-US	3151A1-317-US	
yad Submest	Add Subinvest	Add Subinyest	Add Subinvest	Add Subinvest	Del Subinvest	Name Change	Follow-up	Backgrid Pkg-Request	Delinvest	Add Subinvest	Add Subinvest	Del Subinvest	Del Subinvest	Dei Subinvest	Add Subinvest	Add Subinvest	Del Subinvest	Change in Prot	Change in Prot	
Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Safety Rpt: Clin	Meeting/Telecon	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	
285 IA Correspondence	265 IA Correspondence	265 IA Correspondence	265 IA Correspondence	266 IA Correspondence	268 IA Correspondence	268 IA Correspondence	267 IA Correspondence	268 IA Correspondence	269 IA Correspondence	269 IA Correspondence	269 IA Correspondence	269 IA Carrespondence	269 IA Correspondence	269 IA Correspondence	269 IA Correspondence	270 IA Correspondence	270 lA Correspondence	271 IA Correspondence	272 IA Correspondence	
16-Jun-05	16-Jun-05	16-Jun-05	16-Jun-05	24-Jun-05	24-Jun-05	24~Jun-05	28~Jun-05	14-Jul-05	15-Jul-05	15-Jul-05	15-Jul-05	15-Jul-05	15-Jul-05	15-Jul-05	15-Jul-05	27-Jul-05	27-Jul-05	2-Aug-05	2-Aug-05	
156892 UNITED STATES	156892 UNITED STATES	156892 UNITED STATES	156892 UNITED STATES	1572BD UNITED STATES	157290 UNITED STATES	157290 UNITED STATES	157518 UNITED STATES	158521 UNITED STATES	158610 UNITED STATES	158810 UNITED STATES	158810 UNITED STATES	158810 UNITED STATES	158810 UNITED STATES	158610 UNITED STATES	158810 UNITED STATES	159351 UNITED STATES	159351 UNITED STATES	159648 UNITED STATES	159661 UNITED STATES	

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DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION UNITED S'PRISTIQ	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION UNITED S'PRISTIQ	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-223) FOR THE TREATMENT OF DEPRESSION UNITED S'PRISTIQ									
IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 84,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552
Wyeth	Wyeth	Weth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyath	Wyeth	Wyeth	Wyeth								
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	3151A1-318-US		3151A1-303-WW	3151A1-309-EU	3151A1-308-WW	3151A1-306-US	3151A1-303-WW	3151A1-318-US	3151A1-303-WW	3151A1-303-VWV	3151A1-306-US		3151A1-303-VWV	3151A1-303-WW	3151A1-317-US	3151A1-317-US	3151A1-309-EU	3151A1-303-WW	3151A1-303-WW
Protocol 309-EU statistical analysis plan																			
	Change in Prot	Follow-up	Add Subinvest	Add Research Facil	Add Research Facil	Add Research Facil	Add Research Facil	Del Subinvest	Address Change	Del Subinvest	Address Change	Subm	Add Invest	Add Subinvest	Add Subinvest	Del Subinvest	Address Change	Add IRB	Add Research Facil
Other	Prot Amend	Safety Rpt. Clin	Prot Amend	Prat Amend	Annual Report-IDA	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend							
273 IA Correspondence	274 IA Correspondence	275 IA Correspondence	276 IA Correspondence	278 IA Correspondence	278 IA Correspondence	278 IA Correspondence	276 IA Correspondence	276 1A Correspondence	276 IA Correspondence	276 IA Correspondence	276 IA Correspondence	277 IA Correspondence	278 1A Correspondence	278 IA Correspondence	278 IA Correspondence	278 IA Correspondence	278 IA Correspondence	278 IA Correspondence	278 IA Correspondence
3-Aug-05	4-Aug-05	11-Aug-05	17-Aug-05	14-Sep-05	15-Sep-05	15-Sep-05	15-Sep-05	15-Sep-05	15-Sep-05	15-Sep-05	15-Sep-05								
159712 UNITED STATES	159713 UNITED STATES	160176 UNITED STATES	160411 UNITED STATES	180411 UNITED STATES	160411 UNITED STATES	161659 UNITED STATES	161797 UNITED STATES	161797 UNITED STATES	161797 UNITED STATES	161787 UNITED STATES	161797 UNITED STATES	161797 UNITED STATES	161787 UNITED STATES						

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DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION UNITED S'PRISTIQ	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION								
IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552
Wyeth	Wyeth	Wyeth	Wyet	Wyeth	Wyeth	Wyeth	wyeth	Wyeth	Wyeth	Wyath	Wyath	Wyath	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth
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3151A1-303-WW	3151A1-303-WW				0600D3-175-US	3151A1-309-EU	D600D3-175-US	0600D3-175-US	3151A1-303-WW	0600D3-175-US	3151A1-303-WW			3151A1-303-WW	3151A1-303-WW	3151A1-303-WW	3151A1-303-WW	3151A1-303-WW	
		pre-NDA meebng minutes	Response to FDA Request - Ven Mass Balance study	Pre NDA-CMC meeting request/package									Pre-NDA CMC Type C Meeting.						Updated DS specs & DP manufactured using roller compaction
Address Change	Del Subinvest	Minutes	Information Request		Add Invest	Address Change	Add IRB	Add Research Facil	Del Subinvest	Add Subinvest	Add Subinvest	Follow-up	Minutes	Add Invest	Add Subinvest	Del Subinvest	Add Subinvest	Del Subinvest	
Prot Amend	Prot Amend	Meeting/Telecon	Response to	Info Amend-CMC	Prot Amend	Safety Rpt: Clin	Meeting/Talecon	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Info Amend-CMC						
278 IA Correspondence	278 IA Correspondence	279 IA Correspondence	280 tA Correspondence	281 1A Correspondence	282 IA Correspondence	283 IA Correspondence	284 IA Correspondence	285 IA Conespondence	285 IA Correspondence	285 IA Correspondence	286 IA Correspondence	286 IA Correspondence	287 IA Correspondence						
15-Sep-05	15-Sep-05	27-Sep-05	3-Oct-05	7-Oct-05	13-0ct-05	13-Oct-05	13-Oct-05	13-Oct-05	13-Oct-05	13-0ct-05	13-04-05	14-Oct-05	2-Nov-05	11-Nov-05	11-Nov-05	11-Nov-05	8-Dec-05	8-Dec-05	13-Dec-05
161797 UNITED STATES	161797 UNITED STATES	162277 UNITED STATES	162589 UNITED STATES	162968 UNITED STATES	163351 UNITED STATES	163351 UNITED STATES	163351 UNITED STATES	183351 UNITED STATES	163351 UNITED STATES	163351 UNITED STATES	163351 UNITED STATES	163392 UNITED STATES	164361 UNITED STATES	164910 UNITED STATES	164910 UNITED STATES	164910 UNITED STATES	168430 UNITED STATES	168430 UNITED STATES	166594 UNITED STATES

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UNITED S' PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S' PRISTIG	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S' PRISTIQ	UNITED S' PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S' PRISTIQ	UNITED S' PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ
DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION UNITED S'PRISTIO	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION UNITED S'PRISTIQ						
IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552
Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Weth	Wyeth	Wyeth	Wyeth	Wyeth
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3151A1-303-WW	3151A1-303-WW		3151A1-332-US	3151A1-303-WW	3151A1-333-EU	3151A1-302-WW	3151A1-332-US	3151A1-333-EU		3151A1-900-US	3151A1-198-US	3151A1-303-WW	3151A1-333-EU	3151A1-332-US	3151A1-303-WW	3151A1-332-US		3151A1-801-US	
		Status of Reproductive Fertility Studies																	9-week Juvernie Rat Toxicity Sluidy
Add Subinvest	Del Subinvest	Information Request	New Protocol	Del Subinvest	New Protocol	Change in Prat	Add invest	Add Invest	Follow-up	New Protocol	New Protocol	Add invest	Add Invest	Add Invest	Del Invest	Add Subinvest	Subm	New Protocol	Review/Comment
Prot Amend	Prot Amend	Response to	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Safety Rpt: Clin	Prot Amend	Prot Amend	Annual Report-IDA	Prot Amend	Request					
288 IA Correspondence	288 IA Carrespondence	289 IA Correspondence	290 IA Correspondence	291 IA Correspondence	292 IA Correspondence	293 IA Correspondence	294 IA Correspondence	294 IA Correspondence	295 IA Correspondence	296 IA Correspondence	297 IA Correspondence	298 IA Correspondence	298 M Correspondence	298 IA Correspondence	298 IA Correspondence	298 IA Correspondence	299 IA Correspondence	300 IA Correspondence	301 IA Correspondence
4-Jan-08	4-Jan-06	11-Jan-06	24-Jan-06	3-Feb-06	21-Feb-08	2-Mar-06	3-Mar-06	3-Mar-06	8-Mar-06	15-Mar-06	18-Mar-08	30-Mar-06	30-Mar-06	30-Mar-06	30-Mar-06	30-Mar-06	12-Apr-08	18-Apr-06	24-Apr-08
167468 UNITED STATES	167468 UNITED STATES	167691 UNITED STATES	168172 UNITED STATES	188852 UNITED STATES	189563 UNITED STATES	170271 UNITED STATES	170331 UNITED STATES	170331 UNITED STATES	170857 UNITED STATES	171052 UNITED STATES	171265 UNITED STATES	172348 UNITED STATES	173044 UNITED STATES	173324 UNITED STATES	173883 UNITED STATES				

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UNITED S' PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S' PRISTIQ	UNITED S' PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S' PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S' PRISTIQ	UNITED S'PRISTIQ					
DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION											
IND 64,552	(ND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 84,552	IND 64,552	IND 84,552	IND 64,552	IND 64,552	IND 64,552					
Wyeth	Wyeth	Wyeth	Wyath	Wyeth	Wyeth	Weth	Wyeth	Wyeth	Wyeth	Wyath	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	WAR	W-AR	Wyeth	Wyeth
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	3151A1-333-EU		3151A1-900-US	3151A1-333-EU	3151A1-333-EU	3151A1-333-EU	3151A1-333-EU	3151A1-901-US		3151A1-900-US	3151A1-332-US	3151A1-333-EU	3151A1-333-EU	3151A1-332-US	3151A1-332-US			3151A1-333-EU	3151A1-333-EU
Change in Protocol Amendment 1 for 3151A1-332- US																Submission of SAP for Study 303 (MDD)	Statistical criteria for Amenderant 3		
Change in Prot	Add Invest	Follow-up	Change in Prot	Add invest	Add IRB	Add Research Facil	Add Subinvest	Change in Prot	Change in Prot	Change in Prot	Add invest	Add Subinvest	Del Subinvest	Del Subinvest	Add Subinvest		Review/Comment Req	Add Research Facil	Add IRB
Prot Amend	Prot Amend	Safety Rpt. Clin	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prat Amend	Other	Response to	Prot Amend	Prot Amend
302 IA Correspondence	303 IA Correspondence	304 IA Correspondence	305 IA Correspondence	308 IA Correspondence	306 IA Correspondence	308 IA Correspondence	306 IA Correspondence	307 IA Correspondence	308 IA Conespondence	308 IA Correspondence	309 IA Correspondence	309 IA Correspondence	309 IA Correspondence	309 IA Correspondence	309 tA Correspondence	310 IA Correspondence	311 IA Correspondence	312 IA Correspondence	312 IA Correspondence
28-Apr-08	27-Apr-06	11-May-08		25-May-08	25-May-08	25-May-08	25-May-06	7-Jun-08	8-Jun-08	8-nn-8	7-Jul-08	7-Jul-08	7-141-08	7-34-06	7-34-08	11.114.06	13-101-06	21-54-08	21-Jul-06
173814 UNITED STATES	173997 UNITED STATES	174912 UNITED STATES	175646 UNITED STATES	175805 UNITED STATES	175805 UNITED STATES	175805 UNITED STATES	175805 UNITED STATES	176530 UNITED STATES	176569 UNITED STATES	176569 UNITED STATES	178551 UNITED STATES	176551 UNITED STATES	178551 UNITED STATES	178551 UNITED STATES	178551 UNITED STATES	178888 UNITED STATES	178783 UNITED STATES	178350 UNITED STATES	178350 UNITED STATES

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UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S' PRISTIQ	UNITED S' PRISTIQ	UNITED S' PRISTIQ	UNITED S'PRISTIQ	UNITED S' PRISTIQ	UNITED S' PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S' PRISTIQ	UNITED S'PRISTIQ	UNITED S' PRISTIQ	UNITED S'PRISTIQ
DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION																	
IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	(ND 64,552	IND 64,552												
Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyed	Wyeth	Wyed	Wyed	Wed	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth
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3151A1-333-EU	3151A1-401-US	3151A1-303-WW	3151A1-333-EU	3151A1-332-US	3151A1-303-WW	3151A1-333-EU	3151A1-332-US	3151A1-303-WW	3151A1-333-EU	3151A1-332-US	3151A1-303-WW	3151A1-333-EU	3151A1-333-EU	3151A1-332-US	3151A1-303-WW	3151A1-333-EU	3151A1-332-US	3151A1-303-WW	3151A1-333-EU
Add invest	New Protocol	Add invest	Del Invest	Del IRB	Dei IRB	Add IRB	Add IRB	Add IRB	Add Research Facil	Add Research Facil	Add Research Facil	Address Change	Del RB	Address Change	Address Change	Del Subinvest	Del Subinvest	Del Subinvest	Add Subinvest
Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend												
312 IA Correspondence	313 IA Correspondence	314 lA Correspondence	314 IA Correspondence	314 IA Correspondence	314 IA Correspondence	314 !A Correspondence	314 (A Correspondence	314 IA Correspondence	314 IA Correspondence										
21-Jul-06	9-Aug-06	24-Aug-06	24-Aug-08	24-Aug-06	24-Aug-06	24-Aug-06	24-Aug-06	24-Aug-06	24-Aug-06										
179350 UNITED STATES	180655 UNITED STATES	181584 UNITED STATES	181584 UNITED STATES	161584 UNITED STATES	181584 UNITED STATES	181584 UNITED STATES	161584 UNITED STATES	181584 UNITED STATES	161584 UNITED STATES	181584 UNITED STATES	161584 UNITED STATES	181584 UNITED STATES	181584 UNITED STATES	181584 UNITED STATES	181584 UNITED STATES	181584 UNITED STATES	181584 UNITED STATES	181584 UNITED STATES	181584 UNITED STATES

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UNITED S' PRISTIQ	UNITED S' PRISTIQ	UNITED S' PRISTIQ	UNITED S'PRISTIQ	UNITED S' PRISTIQ	UNITED S'PRISTIQ	UNITED S' PRISTIQ	UNITED S' PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S' PRISTIQ	UNITED S' PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ
DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENIAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION				
IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 84,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552				
Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	W-AR	WAR	W.AR	WAR	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyed	Wyeth
FDA	ą	FDA	Ą	ą	FOA	ą	FDA	FDA	FDA	FDA	FDA	FDA	FDA	FOA	Ą	FDA	FDA	FDA	FD.
3151A1-332-US	3151A1-303-WW	3151A1-332-US	3151A1-332-US	3151A1-303-WW	3151A1-333-EU	3151A1-403-WW			3151A1-335-US	3151A1-800-US	3151A1-332-US	3151A1-401-US	3151A1-332-US	3151A1-335-US	3151A1-403-WW	3151A1-333-EU			3151A1-402-WW
							Submission of duloxetine and a corresponding placebo as a comparator											Submission of comparator Lexapro	
Add Subinvest	Add Subinvest	Del invest	Add Invest	Del Invest	Add Invest	New Protocol		Initial Written	New Protocal	Change in Prot	Change in Prot	Change in Prot	investigator Data	Investigator Data	investigator Data	Investigator Data	Follow-up		New Protocol
Prot Amend	Prot Amend	Prot Amend	Info Amend-CMC	Safety Rpt: Clin	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Safety Rpt: Clin	Info Amend-CMC	Prot Amend				
314 IA Correspondence	314 IA Correspondence	315 IA Correspondence	316 IA Correspondence	317 IA Correspondence	318 IA Correspondence	319 IA Correspondence	320 IA Correspondence	321 IA Correspondence	322 IA Correspondence	322 IA Correspondence	322 IA Correspondence	322 IA Correspondence	323 IA Correspondence	324 IA Correspondence	325 IA Correspondence				
24-Aug-06	24-Aug-06	24-Aug-08	24-Aug-06	24-Aug-06	24-Aug-06	8-Sep-06	15-Sep-06	21-Sep-06	22-Sep-06	27-Sep-06	27-Sep-06	28-Sep-06	13-0ci-06	13-Oct-08	13-0c:-06	13-Oct-06	24-0ct-06	25-Oct-08	3-Nav-06
181584 UNITED STATES	181584 UNITED STATES	194373 UNITED STATES	183133 UNITED STATES	183475 UNITED STATES	183515 UNITED STATES	183784 UNITED STATES	183851 UNITED STATES	183931 UNITED STATES	185019 UNITED STATES	185019 UNITED STATES	185019 UNITED STATES	185019 UNITED STATES	185817 UNITED STATES	185982 UNITED STATES	186700 UNITED STATES				

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DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION UNI)	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION UNITED	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION UNIT	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION UNI	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION UNI	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION UNI	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION UNI	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION UNI	DESVENIJAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION UNI	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION UNITERESTION UNITERESTION UNITERESTION UNITERESTION UNITERESTION UNITERESTICATION UNITERESTI	DESVENIJAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION UNI	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION UNITED	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION UNI	DESVENILAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION UNI	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION UNI	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION UNI	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION UNI	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION UNI	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION UNI	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION UNI
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Wyath	Wyeth	Wyeth	Wyeth	Wyath	Wyeth	Wyath	Wyeth	Wyeth	Wyeth	Wyeth	Wyath	Wyath	Wyeth	Wyeth	Wyath	Wyeth	Wyeth	Wyeth	Wyeth
FDA	Ą	FDA	FDA	FDA	FDA	FDA	ą	FDA	FDA	FDA	Ą	FDA	Ą	FDA	FDA	Ą	FDA	Ą	FDA
3151A1-333-EU	3151A1-403-WW	3151A1-335-US				3151A1-335-US	3151A1-403-WW		3151A1-1203-EU	3151A1-332-US	3151A1-403-WW	3151A1-335-US	3151A1-402-WW	3151A1-333-EU			3151A1-335-US	3151A1-402-WW	
Investigator Data	Investigator Data	Change in Prot	Concurrence	Initial Vertion	Initial Written	Investgator Data	Investigator Data	Fойом-цр	New Protocol	Investigator Data	Investigator Data	Investigator Data	Investigator Data	Investigator Data	Ровом-цр	Initial Written	Investigator Data	Investigator Data	Folowup
Prot Amend	Prot Amend	Prot Amend	Request	Safety Rpt. Clin	Safety Rpt. Clin	Prot Amend	Prot Amend	Safety Rpt. Clin	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Safety Rpt Clin	Safety Rpt: Clin	Prot Amend	Prot Amend	Safety Rpt: Clin
326 IA Correspondence	326 IA Correspondence	327 IA Correspondence	327 IA Correspondence	328 IA Correspondence	329 IA Correspondence	330 IA Correspondence	330 IA Correspondence	331 IA Correspondence	332 IA Correspondence	333 IA Conespondence	333 IA Correspondence	333 IA Correspondence	333 IA Correspondence	333 IA Correspondence	334 IA Correspondence	335 IA Correspondence	336 IA Correspondence	338 IA Correspondence	337 IA Corespondence
9-Nov-06	9-Nov-06	22-Nov-06	22-Nov-08	22-Nov-08	27-Nov-06	15-Dec-08	15-Dec-08	19-Dec-08	20-Dec-08	20-Dec-06	20-Dec-08	20-Dec-06	20-Dec-08	20-Dec-06	21-Dec-08	22-Dec-06	15-Jan-07	15-Jan-07	6-Feb-07
187070 UNITED STATES	187070 UNITED STATES	186007 UNITED STATES	166007 UNITED STATES	188018 UNITED STATES	188147 UNITED STATES	189690 UNITED STATES	189690 UNITED STATES	189891 UNITED STATES	189905 UNITED STATES	189971 UNITED STATES	169871 UNITED STATES	189971 UNITED STATES	169971 UNITED STATES	189971 UNITED STATES	169895 UNITED STATES	190068 UNITED STATES	190984 UNITED STATES	190984 UNITED STATES	182403 UNITED STATES

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DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION UNITED S'PRISTIO	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION
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Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyath	Wyeth	Weth	Weth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Weth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth
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						3151A1-332-US	3151A1-403-WW	3151A1-333-EU	3151A1-402-WW	3151A1-335-US	3151A1-335-US	3151A1-332-US	3151A1-333-EU		3151A1-332-US	3151A1-402-WW	3151A1-403-WW	3151A1-335-US	
														Information on the blinded comparator Paroxetine.					
inital Written	Follow-up	Initial Written	Initial Written	Follow-up	Follow-up	Investigator Data	Investigator Data	Investigator Data	Investigator Data	Investigator Data	Change in Prot	Change in Prot	Change in Prot		Investigator Data	Investigator Data	Investigator Data	Investigator Data	Initial Written
Safety Rpt. Clin	Safety Rpt: Clin	Safety Rpt Clin	Sefety Rpt. Clin	Safety Rpt. Clin	Sefety Rpt. Clin	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Prof Amend	Prot Amend	Info Amend-CMC	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Safety Rpt: Clin
338 IA Correspondence	339 IA Correspondence	340 IA Correspondence	341 IA Correspondence	342 IA Correspondence	343 IA Correspondence	344 IA Correspondence	344 IA Correspondence	344 IA Correspondence	344 IA Correspondence	344 iA Correspondence	345 IA Correspondence	346 IA Correspondence	346 IA Correspondence	347 1A Correspondence	348 IA Correspondence	348 IA Correspondence	348 IA Canespondence	348 IA Correspondence	349 IA Correspondence
8-Feb-07	9-Feb-07	12-Feb-07	14-Feb-07	16-Feb-07	20-Feb-07	1-Mar-07	1-Mar-07	1-Mar-07	1-Mer-07	1-Mar-07	7-Mar-07	12-Mar-07	12-Mar-07	13-Mar-07	15-Mer-07	15-Mar-07	15-Mar-07	15-Mar-07	2-Apr-07
192588 UNITED STATES	192781 UNITED STATES	192850 UNITED STATES	192927 UNITED STATES	193158 UNITED STATES	193343 UNITED STATES	193928 UNITED STATES	193828 UNITED STATES	193926 UNITED STATES	193926 UNITED STATES	193928 UNITED STATES	194271 UNITED STATES	194562 UNITED STATES	194562 UNITED STATES	194565 UNITED STATES	194745 UNITED STATES	194745 UNITED STATES	194745 UNITED STATES	194745 UNITED STATES	196088 UNITED STATES

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DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENIJAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION															
IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 84,552	IND 64,552	IND 64,552	IND 64,552	
Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyath	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	
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3151A1-335-US	3151A1-403-WW	3151A1-402-WW				3151A1-335-US	3151A1-402-WW	3151A1-403-WW	3151A1-336-AP				3151A1-332-US	3151A1-402-WW	3151A1-403-WW		3151A1-402-WW		3151A1-336-AP	
25	ata					वांत्र	eths	egs.	New Protocol and SAP			IND Annual Report	eta	112	era		5		brita	
Investigator Data	Investigator Data	Investigator Data	Initial Written	Follow-up	Follow-up	Investigator Data	Investigator Data	Investigator Data	New Protocol	Inibal Written	Initial Written	Subm	Investigator Data	Investigator Data	Investigator Data	Follow-up	Change in Pro	Follow-up	Investigator Data	
Prot Amend	Prot Amend	Prot Amend	Safety Rpt. Clin	Safety Rpt. Clin	Safety Rpt. Clin	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Sarlety Rpt Clin	Safety Rpt: Clin	Annual Report-IDA	Prot Amend	Prot Amend	Prot Amend	Safety Rpt Clin	Prot Amend	Safety Rpt Clin	Prot Amend	
350 (A Conespondence	350 IA Correspondence	350 IA Correspondence	351 IA Correspondence	352 IA Correspondence	353 IA Correspondence	354 IA Correspondence	354 IA Correspondence	354 IA Correspondence	355 (A Correspondence	358 IA Correspondence	357 IA Correspondence	358 IA Correspondence	359 IA Correspondence	359 IA Correspondence	359 IA Correspondence	360 IA Correspondence	361 IA Correspondence	382 IA Correspondence	383 IA Carrespondence	
6-Apr-07	8-Apr-07	6-Apr-07	10-Apr-07	18-Apr-07	28-Apr-07	8-May-07	8-May-07	8-May-07	17-May-07	17-May-07	25-May-07	31-May-07	6-Jun-07	8-Jun-07	8-Jun-07	12-Jun-07	14-Jun-07	20-Jun-07	27-Jun-07	
196868 UNITED STATES	196668 UNITED STATES	196668 UNITED STATES	196865 UNITED STATES	197389 UNITED STATES	198111 UNITED STATES	199156 UNITED STATES	198158 UNITED STATES	189158 UNITED STATES	199838 UNITED STATES	199897 UNITED STATES	200655 UNITED STATES	201023 UNITED STATES	201503 UNITED STATES	201503 UNITED STATES	201503 UNITED STATES	201918 UNITED STATES	202107 UNITED STATES	202581 UNITED STATES	203066 UNITED STATES	

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DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION UNITED S' PRISTIO										
IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	
Wyeth	Wyeth	Wyath	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Weth	Wyeth	Wyeth	Weth	Wyeth	Wyeth	Wyeth	
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3151A1-402-WW	3151A1-335-US	3151A1-402-WW	3151A1-403-WW				3151A1-336-AP	3151A1-402-WW		3151A1-336-AP	3151A1-335-US	3151A1-403-WW	3151A1-402-WW				3151A1-336-AP	3151A1-402-WW	3151A1-403-WW	
																Final Statistical Analysis Plan for Study 335-US				
Investigator Data	Investigator Data	Investigator Data	Investgator Data	Initial Written	Initial Written	Initial Written	Investigator Data	Investigator Data	Follow-up	Change in Prot	Add Invest	Add Invest	Addinvest	Follow-up	Initial Whitten		Investigator Data	Investigator Data	Investigator Data	
Prot Amend	Prot Amend	Prot Amend	Prot Amend	Safety Rpt. Clin	Safety Rpt. Clin	Safety Rpt: Clin	Prot Amend	Prot Amend	Safety Rpt. Clin	Prot Amend	Prot Amend	Prot Amend	Prot Amend	Safety Rpt. Clin	Safety Rpt: Clin	Other	Prot Amend	Prot Amend	Prot Amend	
363 IA Correspondence	364 IA Correspondence	384 IA Correspondence	384 IA Correspondence	365 IA Correspondence	386 IA Correspondence	367 IA Correspondence	368 IA Correspondence	368 IA Carrespondence	369 IA Correspondence	370 IA Correspondence	371 IA Correspondence	371 IA Correspondence	371 IA Correspondence	372 IA Correspondence	373 IA Correspondence	374 IA Correspondence	375 IA Correspondence	375 IA Correspondence	375 IA Correspondence	
27-Jun-07	28-Jul-07	26-Jul-07	26-341-07	1-Aug-07	2-Aug-07	17-Aug-07	23-Aug-07	23-Aug-07	31-Aug-07	17-Sep-07	19-Sep-07	19-Sep-07	19-Sep-07	2-Oct-07	10-001-07	17-Oct-07	18-00-07	18-0ct-07	18-Oct-07	
203066 UNITED STATES	205338 UNITED STATES	205330 UNITED STATES	205338 UNITED STATES	205840 UNITED STATES	206045 UNITED STATES	207165 UNITED STATES	207881 UNITED STATES	207881 UNITED STATES	208285 UNITED STATES	209223 UNITED STATES	209849 UNITED STATES	209949 UNITED STATES	209949 UNITED STATES	211301 UNITED STATES	212015 UNITED STATES	212919 UNITED STATES	213039 UNITED STATES	213039 UNITED STATES	213039 UNITED STATES	

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DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION								
IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 84,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 84,552	IND 64,552
Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Weth	Wyeth	Wyeth	Wyeth	Weth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth
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		3151A1-402-WW			3151A1-403-WW	3151A1-336-AP				3151A6-2000-US					3151A6-2001-US	3151A1-402-WW	3151A1-403-VWV		3151A6-2000-US
			To submit 10/25 mg CMC information						Pedatric Study Request										
Follow-up	Follow-up	Investigator Data		Follow-up	Investigator Data	Change in Prot	7-Day P/F & Initial	7-Day P/F & Initial		New Protocol	Initial Written	7-Day PrF & initial	Follow-up	Follow-up	New Protocol	Investigator Data	Investigator Data	f olow-up	Investigator Data
Safety Rpt: Clin	Safety Rpf. Clin	Prot Amend	Info Amend-CMC	Safety Rpt: Clin	Prot Amend	Prot Amend	Safaty Rpt. Clin	Safety Rpt. Clin	Other	Prot Amend	Safety Rpt. Clin	Safety Rpt. Clin	Safety Rpt: Clin	Safety Rot: Clin	Prot Amend	Prot Amend	Prot Amend	Safety Rpt: Clin	Prot Amend
378 IA Correspondence	377 IA Correspondence	378 IA Correspondence	379 IA Correspondence	360 IA Correspondence	361 IA Correspondence	382 tA Correspondence	383 IA Correspondence	383 IA Correspondence	384 IA Carrespondence	365 IA Correspondence	386 IA Correspondence	366 IA Correspondence	367 IA Carrespondence	388 IA Correspondence	389 IA Correspondence	390 IA Correspondence	390 LA Correspondence	391 IA Correspondence	392 IA Correspondence
23-0ct-07	25-04-07	15-Nov-07	6-Dec-07	10-Dec-07	11-Dec-07	17-Dec-07	17-Dec-07	17-Dec-07	18-Dec-07	19-Dec-07	19-Dec-07	19-Dec-07	20-Dec-07	2-Jan-08	3-Jan-08	15-Jan-08	15-Jan-08	18-Jan-08	17-Jan-08
213396 UNITED STATES	213647 UNITED STATES	215529 UNITED STATES	216773 UNITED STATES	217784 UNITED STATES	216016 UNITED STATES	216614 UNITED STATES	218815 UNITED STATES	218710 UNITED STATES	218897 UNITED STATES	218721 UNITED STATES	218777 UNITED STATES	218306 UNITED STATES	219057 UNITED STATES	219255 UNITED STATES	219304 UNITED STATES	220802 UNITED STATES	220802 UNITED STATES	221239 UNITED STATES	221260 UNITED STATES

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DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION UNITED S'PRISTIQ																				
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3151A1-335-US	3151A1-403-WW	3151A1-402-WW	3151A6-2000-US			3151A1-336-AP	3151A6-2001-US	3151A1-402-WW	3151A6-2000-US	3151A1-403-WW	3151A6-2001-US									
														Additional Desk Copies of IND - Cover Memo Only	Addtional Copy of Imbal IND					
Investigator Data	Investigator Data	Investigator Data	Investigator Data	Initial Written	Follow-up	Investigator Data	Change in Prot	Follow-up	into	Other	Other	info Request-Respon	Clinical Issues	Cilrical Issues	Clinical Issues					
Prot Amend	Prot Amend	Prot Amend	Prot Amend	Safety Rpt: Clin	Safety Rpt: Clin	Prot Amend	Safety Rpt. Clin	Request	Inibal IDA	Initial IDA	CMC Issues	Phone	Phone	Phone						
393 IA Correspondence	393 IA Correspondence	393 IA Correspondence	393 IA Correspondence	394 IA Correspondence	395 IA Correspondence	396 IA Correspondence	396 IA Correspondence	398 IA Correspondence	396 IA Correspondence	396 IA Correspondence	397 IA Correspondence	398 IA Correspondence	IA Correspondence	IA Correspondence	IA Correspondence	IA Conespondence	IDA-FDA Con Rpt	IDA-FDA Con Rpt	IDA-FDA Con Rpt	
15-Feb-08	15-Feb-08	15-Feb-08	15-Feb-08	29-Feb-08	11-Mar-08	14-Mar-08	14-Mar-05	14-Mar-08	14-Mar-08	14-Mar-08	20-Mar-08	21-Mar-08	22-Apr-02	19-Apr-02	18-Apr-02	2-May-02	24-Oct-03	23-0ct-03	24-Oct-03	
223909 UNITED STATES	223906 UNITED STATES	223906 UNITED STATES	223908 UNITED STATES	225077 UNITED STATES	225601 UNITED STATES	225881 UNITED STATES	225581 UNITED STATES	225861 UNITED STATES	225861 UNITED STATES	225861 UNITED STATES	228429 UNITED STATES	226523 UNITED STATES	105186 UNITED STATES	105187 UNITED STATES	105190 UNITED STATES	105633 UNITED STATES	129575 UNITED STATES	128581 UNITED STATES	128560 UNITED STATES	

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DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION										
IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64.552	IND 64,552						
Ā	FDA	Wyeth	Wyeth	Wyeth	FDA	FDA	Wyeth	FDA	FDA	FDA	PDA	Wyeth	Wyeth	FD.	PD	Wyeth	FDA	Wyeth	AQ.
Wyeth	Wyeth	FDA	Wyeth	FDA	Wyeth	Wyeth	Ą	Wyeth	Wyeth	Wyeth	Wyeth	FDA	FDA	Wyath	Wyeth	Ą	Wyeth	FDA	Wyeth
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						NO DOC	NO DOC	FDA Commendations re New Prot Submission, 0600D3-172- US	Clinical Trials Data Bank Info	re; 060003-170-EU study			NO DOC	Advice on dose selection.	Agency finds protocol #3151A1-900-US acceptable.	Miscellaneous issues.	NO DOC	NO DOC	NO DOC
info	info	Information Request	Meeting Sched/Issues	Review/Comment	Review/Comment Req			Other	Other	Information-Request	Information-Request	Into Request-Respon		Other	New Protocol				
Request	Request	Response to	Phone	Request	Response to	Mig Min (Ne Dec)	Mtg Min (No Doc)	Protocol-Clinical	Clinical Issues	Protocol-Clinical	CMC Issues	CMC Issues	Other	Non-Clinical Issues	Prot Amend	Gen Corr	Mtg Min (Na Dac)	Mtg Min (No Doc)	Mtg Min (No Doc)
IA Correspondence	IA Correspondence	M Correspondence	IDA-FDA Con Rpt	IA Correspondence	IA Carespandence	LA-GRR Note to File	IA-GRR Note to File	IA Correspondence	IA Correspondence	iA Correspondence	IA Correspondence	IA Correspondence	IA-GRR Note to File	IA Correspondence	IA Correspondence	IA Correspondence	IA-GRR Note to File	IA-GRR Note to File	IA-GRR Note to File
14-Mar-03	25-Aug-03	2-Sep-03	7-Aug-03	14-Feb-03	31-74-03	28-Feb-03	4-Feb-03	30-Oct-02	30-Sep-02	6-May-02	6-May-02	6-May-02	20-May-05	20-141-08	26-hm-08	80-un/-8	27-001-05	27-04-05	8-Sep-05
126162 UNITED STATES	127320 UNITED STATES	127319 UNITED STATES	127235 UNITED STATES	126119 UNITED STATES	126107 UNITED STATES	126020 UNITED STATES	125987 UNITED STATES	113475 UNITED STATES	112888 UNITED STATES	112580 UNITED STATES	112587 UNITED STATES	108455 UNITED STATES	181420 UNITED STATES	179393 UNITED STATES	178414 UNITED STATES	178705 UNITED STATES	175428 UNITED STATES	175419 UNITED STATES	175379 UNITED STATES

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UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S'PRISTIQ	UNITED S' PRISTIQ	UNITED S' PRISTIQ	UNITED S' PRISTIQ	UNITED S'PRISTIQ	UNITED S' PRISTIQ	UNITED S'PRISTIQ	UNITED S' PRISTIQ	UNITED S'PRISTIQ	UNITED S' PRISTIQ	UNITED S'PRISTIQ	UNITED S' PRISTIQ	UNITED S'PRISTIQ	UNITED S' PRISTIQ	UNITED S'PRISTIO	UNITED S'PRISTIC	UNITED S' PRISTIQ	UNITED S'PRISTIQ
DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION UNITED S'PRISTIQ	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESVENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION	DESYENLAFAXINE SUCCINATE (DVS-233) FOR THE TREATMENT OF DEPRESSION UNITED S'PRISTIO						
IND 64,552	IND 64,552	IND 84,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64.552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552	IND 64,552					
Wyath	FDA	Wyeth	FOA	FDA	Wyeth	FDA	Wyeth	Wyeth	FDA	FDA	FDA	Wyeth	Wyeth	FDA	Wyeth	FDA	FDA	Wyeth	Wyeth
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NO DOC	NO DOC	NO DOC	SN 293 Review.	Answer to question on the Toxicology Amendment.	Interpretation of e-mail on Toxicology amendment.	Toxicology amendment.	Question on toxicology reports.	Acknowledged receipt of e- mail dated 18-AUG-05.	include conversation with Dr. Oliver regarding the stability data.	27-OCT-2005 Teleconference.	Discuss Pre-NDA CMC issues.	Stability Data.	Acknowledged receipt of e- mail dated 28-NOV-2005 - statistical comments.	Resending message dated 25- NOV-2005 - statistical comments.	To obtain concurrence from the Agency.	Minutes and overheads of 4- 10-03.	Type C meeting to be held 27- OCT-2005.	Teleconference scheduled for 27-OCT-2005.	Teleconference scheduled for 27-OCT-2005.
			Review/Comment Req	information Request		Information Request	Info		Info	Minutes	Minutes	Other			General	Minutes	Confirm	Meeting Sched/issues	CMC issues
Mtg Min (No Doc)	Mtg Min (No Doc)	Mtg Min (No Doc)	Response to	Response to	Gen Corr	Response to	Request	Gen Corr	Meeting/Telecon	Meeting/Telecon	Meeting/Telecon	CMC Issues	Gen Corr	Gen Corr	Phone	Meeting/Telecon	Meeting/Telecon	Phone	Porose •
IA-GRR Note to File	IA-GRR Note to File	IA-GRR Note to File	IA Correspondence	iA Correspondence	IA Correspondence	IA Correspondence	1A Correspondence	IA Correspondence	IA Correspondence	IA Correspondence	IA Correspondence	LA Correspondence	IA Correspondence	IA Correspondence	IDA-FDA Con Rpt	iA Correspondence	IA Correspondence	IDA-FDA Con Rpt	IDA-FDA Con Rpt
20-Sep-05	15-Jun-05	15-Jun-05	20-Apr-06	27-Jan-06	23-Jan-08	23-Jan-06	20-Jan-06	26-Aug-05	18-Dec-05	8-Dec-05	25-Nov-05	23-Nov-05	28-Nov-05	28-Nov-05	23-Nov-05	28-Apr-03	18-Oct-05	21-0ct-05	21-04-05
175371 UNITED STATES	175237 UNITED STATES	175234 UNITED STATES	173583 UNITED STATES	168476 UNITED STATES	168123 UNITED STATES	168122 UNITED STATES	168113 UNITED STATES	167818 UNITED STATES	187519 UNITED STATES	167517 UNITED STATES	166938 UNITED STATES	165927 UNITED STATES	165604 UNITED STATES	165603 UNITED STATES	165601 UNITED STATES	164750 UNITED STATES	164425 UNITED STATES	164201 UNITED STATES	164201 UNITED STATES

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Wyeth	FDA	FDA	Wyeth	Wyath	Wyeth	Wyeth	Wyeth	Wyeth	FDA	Wyeth	FDA	Wyeth	FDA	Wyeth	Wyeth	Wyath	Wyeth	FDA	Wyeth
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There will be no additional question to include to the meeting package.	eCTD interactive demonstration.	Telecon granted 27-OCT-05.	Minutes and Presentation of 20-SEP-05 CMC Pilot Program.	Data correction - 27-OCT-05.	Tentatively scheduled 20-OCT. 05	Teleconference information for 27-0CT-2005.	Confirmed receipt of the CMC meeting request and information package.	CMC meeting package scheduled 27-0CT-05.	Minutes of 8-SEP-05.	eCTD interactive demonstration.	Type C meeting scheduled for 20-SEP-05. Discuss CMC information.	Detailed feedback requested of the meeting held 8-SEP-05.	Accepted to the Pilot program.	Information regarding 8-SEP- 05 meeting.		Power Point Side presentation for 8-SEP-05 meeting	Additional questions.	Acknowledged e-mail receipt.	Provide fist of questions requested by the Agency.
Other		Mtg Req-Response	Minutes	into	trito	Into	CMC Issues	into	Minutes		Confirm	info	Infa Request-Respon	Info	otol	Info	info		Information Request
CMC Issues	Gen Corr	Meeting/Telecon	Meeting/Telecon	Meeting/Telecon	Meeting/Telecon	Meeting/Telecon	Phone	Mesting/Telecon	Meeting/Telecon	Gen Con	Meeting/Telecon	Mesting/Telecon	CMC issues	Mesting/Telecon	Meeting/Telecon	Meeting/Talecon	Meeting/Telecon	Gen Con	Response to
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21-Oct-05	20-Oct-05	19-04-05	28-Sep-05	11-Oct-05	10-Oct-05	13-00-05	11-Oct-05	5-0-1-05	30-Sep-05	29-Sep-05	8-Sep-05	20-Sep-05	1-Sep-05	7-Sep-05	6-Sep-05	7-Sep-05	25-Aug-05	24-Aug-05	24-Aug-05
164171 UNITED STATES	183801 UNITED STATES	163770 UNITED STATES	183636 UNITED STATES	183543 UNITED STATES	163542 UNITED STATES	163539 UNITED STATES	183406 UNITED STATES	183034 UNITED STATES	162696 UNITED STATES	182487 UNITED STATES	162069 UNITED STATES	162039 UNITED STATES	161861 UNITED STATES	161521 UNITED STATES	161513 UNITED STATES	161510 UNITED STATES	160923 UNITED STATES	160790 UNITED STATES	160789 UNITED STATES

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Will provide information requested on 22-AUG-05.	questions on page 10-11 of the 7-14-05 briefing document.	FDA CMC pilot program	Request to participate in the Agency's CMC pilot program.	FDA CMC pilot program.	formal written request to participate in FDA CMC pilot program.	Submission feedback letter received.	Submission feedback	Pediatric Waiver and Deferral S/N 223.	Meeting/Telecon held on 15- JUN-05.	Type B meeting confirmed for 8-AUG-05.	Meeting granted 9-6-05.	Quality by Design approach meeting 15-JUN-05.	Drug interaction study development plan.	Notification of the requested data on 217, 219 & 226.	Desk copies of 1/11, 1/14 and 2/1/2005 submissions	Inclusion of Executed Datch Records, Sustained versus Extended Release terminology.	Submission feedback.	15-JUN-05 to discuss Quality by Design approach.	Meeting scheduled for 15-JUN- 05 to factures 101 A 08 "Quality by Design" approach and its applicability to upcoming NDA	
	Info	Mesting-Request	Other	CMC Issues	Info	senssi		otr.	Minutes	Confirm	Mtg Req-Response	Minutes	Review/Comment Req		Other	CMC Issues		Confirm	Meeting Sched/Issues	
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23-Aug-05	22-Aug-05	18-Aug-05	11-Aug-05	11-Aug-05	11-Aug-05	4-Aug-05	3-Aug-05	25-Jul-05	14-Jul-05	22-Jul-05	20-701-05	20-Jun-05	14-Jun-05	2-Jun-05	27-May-05	27-May-05	4-May-05	22-Apr-05	22-Apr-05	
160768 UNITED STATES	160767 UNITED STATES	160520 UNITED STATES	180428 UNITED STATES	160365 UNITED STATES	180219 UNITED STATES	160061 UNITED STATES	159810 UNITED STATES	159193 UNITED STATES	159143 UNITED STATES	159132 UNITED STATES	159067 UNITED STATES	157528 UNITED STATES	158900 UNITED STATES	156155 UNITED STATES	155909 UNITED STATES	155780 UNITED STATES	154410 UNITED STATES	154274 UNITED STATES	153604 UNITED STATES	

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Feedback on submission S/N 223 & 242.	Meeting to discuss Wyeth's proposal for Quality by Design Approach!	Discuss ICHQ8 Risk Based Approach.	FDA Feedback	Requests and recommendations on submissions SAN 151 & 161.	Meeting cancelled 31-JAN-05.	Requesting 21-JAN-05 meeting attendees names	Additional information requested 11-JAN-05 Teleconference.	NO DOC	e-mail received and able to view the document.	12-JAN-05 Info request	List of participants in the 11- JAN-05 telecon.	Additional information requested on the 11-JAN-05 telecon.	To clarify the submitted IVIVC.	Additional Information in support of January 21 Type B meeting for Biowaiver for 150 mg.	Concur with the DRUDP's review.	Seeking confirmation of designation of Methoxyacetate as starting material.	Confirmation of designation of Methoxyacetate as starting material.	Issues regarding S/N 144.	Feecdback on submission dated 21-JUL-D-4 (S/N 169).
Guidance	Meeting-Request	Meeting-Request		Other	Other	Request - Other	Information-Request			Information Request	Info	Information Request	Meeting-Request	CMC Issues		Information-Request	CMC Issues		Review/Comment
Request	Meeting/Telscon	Meeting/Telecon	Gen Corr	Clinical Issues	Meeting/Telecon	Meeting/Telecon	CMC (ssues	Mtg Min (No Doc)	Gen Corr	Response to	Meeting/Telecon	Response to	Meeting/Telecon	Phone	Gen Corr	CMC (ssues	Phone	Other	Request
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21-Apr-05	1-Apr-05	21-Mar-05	16-Feb-05	15-Feb-05	28-Jan-05	11-Jan-05	12-Jan-05	11-Jan-05	19-Jan-05	18-Jan-05	11-Jan-05	12-Jan-05	6-Jan-05	11-Jan-05	15-Nov-04	8-Nov-04	B-Nov-04	5-Nov-04	22-Oct-04
153543 UNITED STATES	152354 UNITED STATES	151769 UNITED STATES	149932 UNITED STATES	149707 UNITED STATES	146959 UNITED STATES	148748 UNITED STATES	148746 UNITED STATES	148719 UNITED STATES	148389 UNITED STATES	148343 UNITED STATES	147892 UNITED STATES	147991 UNITED STATES	147975 UNITED STATES	147938 UNITED STATES	145060 UNITED STATES	144621 UNITED STATES	144820 UNITED STATES	144818 UNITED STATES	144059 UNITED STATES

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Comments on the submissions dated 21-JUL-04 and 16-SEP-04.	Requirements for a Pediatric development program.	Question on the future product labeling.	Status of FDA feedback on submissions S/N 146 and 157.		FDA cannot comment on how Wyeth discontinuation scale will impact labeling	Feedback on the S/N 157 and 148.	Response to status of submissions dated 02-JUN-04, 17-JUN-04 & 21-JUL-04.	Request for status of submissions dated 02-JUN-04, 17-JUN-04 & 21-JUL-04.	Status of FDA feedback on submissions S/N 149 and 157.	NO DOC EDA monting for feathers from	the Cardio consultants to respond to our request for feedback.	Requested feedback on our proposed QTc clinical study.	Submission (1-2/-04) recommendations and comments from the Office of Biometrics	Question about pediatric written requests for MDD studies	Request for feedback on draft QT protocol.	Request for feedback on a draft QT protocol.	Documents received	NO DOC	
info Requesi-Respon	Pediatric Ex Issues	Info	Info		Information Request	Review/Comment Req	Review/Comment Req	Review/Comment	Info			Review/Comment		Issues	Other	Clinical Issues	senssi		info
Citnical Issues	Phone	Request	Request	Gen Corr	Response to	Response to	Response to	Request	Request	Other	Gen Corr	Request	Gen Corr	Pediatric Exclus	Phone	Phone	Pediatric Exclus	Mtg Min (Na Doc)	Request
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FDA completed review of April 1, 2003 substants and there recommendations regarding findings in the fertility and development toxicity study in 183.	response to Serial 008	Comments regarding Statistical plan.									Missed Serial #120 - Should be no problem	Inform FDA that there will no serial #120	Clinical and Pherm/Tox comments		Request clarification to 2/25 e- mail	Request clarification to 225 e- mail	re: Safety Concern Issues; FDA Review of Prot - Perm to Proceed	re: Safety Concern Issues; FDA Review of Prot - Perm to Proceed	FDA wating for a desk copy
Other	Review/Comment Req	Info Request-Respon	Information Request	Information-Request	Info Request-Respon	Information-Request	Info Request-Respon	Info Request-Respon	Other		Other			Revised	Information Request		Octobe		
Protocol-Clinical	Response to	Clinical Issues	Response to	CMC Issues	CMC issues	CMC issues	CMC Issues	CMC issues	CMC issues	Perm to Proceed	Response to	Gen Con	Gen Corr	Prot Amend	Response to	Gen Corr	Safety Issues	Perm to Proceed	Other
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Increase dose from 200mg to 400 mg		Dose adjustment	Urgent Feedback sent to FDA	Nov 6th mtg	And See GOTH STATE AND	NO DOC	permission to proceed				Wyeth seeks to speak to statistical reviewer regarding comment on multiplicity.		Questions about Pediatric Written Requests for MDD Studies	corrected background info., participants list and mtg questions	Ackn Rept - April 10, 2003 Mtg Minutes				
				Minutes	8		Info Request-Respon	Clinical Issues	Clinical Issues	Review/Comment		Minutes	Written Request	Info	Minutes	Review/Comment	Information Request	Information Request	
Gen Carr	Gen Corr	Ogje	Gen Con	Meeting/Telecon	into Amend-Pharm7 ox	Mtg Min (No Doc)	Protocol-Clinical	Phone	Phone	Request	Other	Meeting/Talecon	Pediatric Exclus	Meeting/Telecon	Meeting/Telecon	Request	Response to	Response to	
A Correspondence	IA Correspondence	IA Correspondence	IA Correspondence	IA Correspondence	IA Correspondence	IA-GRR Note to File	IA Correspondence	IDA-FDA Con Rpt	IDA-FDA Con Rpt	IA Correspondence	IA Correspondence	1A Correspondence	IA Correspondence	IA Correspondence	1A Correspondence	IA Correspondence	IA Correspondence	iA Correspondence	
5-Feb-04	5-Feb-04	13-Feb-04	13-Feb-04	25-Nov-03	24-Jul-03	10-Apr-03	19-May-03	11-Jun-03	8-un-63	28-May-03	28-May-03	17-Apr-03	21-Jan-04	4-Apr-03	22-Apr-03	20-Feb-03	31-Jan-03	29-Jan-03	
134306 UNITED STATES	134514 UNITED STATES	134409 UNITED STATES	134153 UNITED STATES	132252 UNITED STATES	125568 UNITED STATES	124568 UNITED STATES	124244 UNITED STATES	123103 UNITED STATES	123018 UNITED STATES	122628 UNITED STATES	122336 UNITED STATES	121328 UNITED STATES	133148 UNITED STATES	121327 UNITED STATES	120765 UNITED STATES	117876 UNITED STATES	117857 UNITED STATES	117855 UNITED STATES	

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FDA Mtg Minutes - EOP2 02/04/03 Mtg	FDA sent e-mail confirming receipt of Wyeth's response to FDA Request for Pharma cokinetic data (serial no. 041)	request for clarification forwarded	FDA comments on May 28th and Sept 3rd, 5th and 8th submissions	re: submission on May 29, Sep 3, 5, 8 B	comments and recommendations regarding 3151A1-303-WWW for the SR	comments and recommendations regarding 3151A1-303-WWW for the SR		NO DOC	looking for feedback on Serial 069	response to chinical portion (serial no. 085) attached as pdf	response to: when will we receive comments on serial 069?		Permission to proceed with comments on 3 new protocols						
Minutes			Other	Review/Comment Req	Other	Other	CMC Issues		Review/Comment	information Request	Information Request	Clinical Issues	Info Request-Respon	Request-Response	Response Req - Other	Confirm	Change in Prot	Info Request-Respon	Information-Request
Meeting/Telecon	Gen Cort	Gen Corr	CMC issues	Response to	Protocol-Clinical	Protocol-Clinical	Phone	Other	Request	Response to	Response to	Phone	Protocol-Clinical	Meeting/Telecon	Meeting/Telecon	Meeting/Telecon	Prot Amend	CMC issues	CMC Issues
LA Correspondence	IA Correspondence	IA Correspondence	IA Correspondence	IA Correspondence	IA Correspondence	IA Correspondence	IDA-FDA Con Rpt	IA-GRR Note to File	(A Correspondence	IA Correspondence	IA Correspondence	IDA-FDA Con Rpt	IA Correspondence	IA Correspondence	IA Correspondence	IA Correspondence	iA Correspondence	iA Correspondence	A Carrespondence
3-Mar-03	29-Jan-03	6-May-02	12-Nov-03	12-Nov-03	23-Sep-03	23-Sep-03	9-Oct-03	15-Apr-03	23-Sep-03	12-Sep-03	12-Sep-03	12-Sep-03	19-May-03	6-Dec-02	6-Dec-02	2-Dec-02	13-Aug-02	26-Apr-02	28-401-02
117654 UNITED STATES	116920 UNITED STATES	115093 UNITED STATES	131579 UNITED STATES	130423 UNITED STATES	129384 UNITED STATES	129372 UNITED STATES	128897 UNITED STATES	128416 UNITED STATES	128358 UNITED STATES	128112 UNITED STATES	128104 UNITED STATES	127909 UNITED STATES	122269 UNITED STATES	114726 UNITED STATES	114725 UNITED STATES	114517 UNITED STATES	110596 UNITED STATES	109381 UNITED STATES	109360 UNITED STATES

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		Whether seeking above, whether beckground information and proposed protocols can be submitted under one serial number for each protocol			The has safety concerns regarding DV6-233 SR Tablets regarding proposed dose levels due to observations of tachycardia & typertension. FDA requested	phermacokinete stead-state profiles of DVS-23 SR tablets data & simulated profiles for 100, 200 & 400 mg doses.						IND in effect					re: Clinical Trial Data Bank		
Information Request	Pediatric Ex Issues	Other	<u>of a</u>	Guidance Request	Safety Issues	Clinical Issues	Meeting Schedissues	양대	Other	Pediatric Ex Issues	Clinical Issues	General	Curical Issues	Clinical Issues	Information Request	Information Request	Other	Clinical (ssues	
Response to	Phone	Protocol - Non-Clin	Meeting/Telecon	Response to	Phone	Phone	Phone	Meeting/Telecon	Clinical Issues	Phone	Phone	Phone	Phone	Phone	Response to	Response to	Clinical Issues	Phone	
iA Correspondence	IDA-FDA Con Rpt	IA Correspondence	IA Correspondence	iA Correspondence	IDA-FDA Con Rpt	IDA-FDA Con Rpt	IDA-FDA Con Rpt	IA Correspondence	iA Correspondence	IDA-FDA Con Rpt	IDA-FDA Con Rpt	IDA-FDA Con Rpt	IDA-FDA Con Rpt	IDA-FDA Cen Rpt	IA Carrespondence	M Correspondence	IA Correspondence	IDA-FDA Con Rpt	
6-May-02	24-Jun-02	15-Jan-03	23-Jan-03	16-Jen-03	30-Jan-03	28-Jan-03	24-Jan-03	22-Jan-03	11-Jun-02	4-Jun-02	4-Jun-02	10-May-02	8-May-02	6-May-02	6-May-02	2-May-02	4-Jun-02	19-Jun-02	
108742 UNITED STATES	106561 UNITED STATES	116592 UNITED STATES	118588 UNITED STATES	118581 UNITED STATES	116434 UNITED STATES	116197 UNITED STATES	116097 UNITED STATES	116050 UNITED STATES	107562 UNITED STATES	10684D UNITED STATES	106640 UNITED STATES	105803 UNITED STATES	105893 UNITED STATES	105691 UNITED STATES	105880 UNITED STATES	105633 UNITED STATES	107620 UNITED STATES	107628 UNITED STATES	

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	Additional Copy of Infast IND		Requesting Additional Copies of IND	Requesting Additional Copies of IND		re: incorrect receipt date	re: incorrect Receipt Date
Waiver Req-Respon	Information Request	O Bear	Other	info	Acknowledge Receipt	Issues	Issues
Pediatric Exclus	Response to	CMC Issues	Initial IDA	Request	Initial IDA	Initial IDA	Initial IDA
IA Correspondence	IA Correspondence	iA Carrespondence					
11-Jun-02	18-Apr-02	22-Apr-02	18-Apr-02	18-Apr-02	18-Apr-02	25-Apr-02	26-Apr-02
107582 UNITED STATES	105190 UNITED STATES	105414 UNITED STATES	105191 UNITED STATES	105191 UNITED STATES	105312 UNITED STATES	105314 UNITED STATES	105319 UNITED STATES

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App. Region								
App. Description	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)							
App.#	NDA 21-992							
From	Wyeth	Wyeth	Wyeth	FDA	Wyeth	Wyeth	Wyeth	Wyeth
4	Wyeth	d-05 FDA	Wyeth	9-Nov-05 Wyeth	Wyeth	FDA	12-Nov-05 FDA	22-Dec-05 FDA
Email Date		d. 11.		9. 3.				
Chronology Description	NDA number assigned.	Feedback requested: 11-Oct-05 FDA	Outstanding NDA items.	Agency requests a literature search.	Literature search.		Preclinical TOC and ECG tracings.	Delivery and Holiday week notification.
Sub3 Type						ç		
Sub2 Type	General	Info	General	Re Info	General	-Submissio	Сопеѕр	Соптехр
Sub1 Type	A C Phone	xres Request	A C Phone	xres Resp to Re Info	JA C Phone	MA-User F Payment-Submission	MA-Corres General Corresp	MA-Corres General Corresp
Doc.	MA-FDA C	MA-Corres	MA-FDA C	MA-Corres	MA-FDA C	MA-U	MA-C	MA-C
Reference Doc. Doc. Date # Type	27-Sep-05	11-Oct-05	1-Nov-05	9-Nov-05	9-Nov-05	9-Nov-05	12-Nov-05	22-Dec-05
Grits Doc ID App. Country	162838 UNITED STATES 27-Sep-05	163294 UNITED STATES 11-00-05	164424 UNITED STATES	164844 UNITED STATES	164931 UNITED STATES	170885 UNITED STATES	165026 UNITED STATES	167353 UNITED STATES

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FDA	28-Dec-05 Wyeth	29-Dec-05 wyeth	31-Dec-05 FDA	11-Jan-06 FDA	20-Jan-06 FDA	20-Jan-06 FDA	23-Jan-06 Wyeth	FDA
	Schedule training session for eCTD.	Saved date of 8-FEB- 2006 for training session of eCTD.	Will confirm details after meeting the eCTD team.	Requests and questions prior to the meeting on 8-FEB-2006.	Answers to questions 1 through 5.	Acknoledged receipt of e-mail.	Request additional 8 desk copies for the meeting to be held on 13-FEB-2006.	Pilot Program Meeting.
MA-(Origin: Orig Full Subm	MA-Corres Mtg/Teleco Request for Meeting	MA-Corres; Mtg/Teleco Info	MA-Corres Mtg/Teleco Other	MA-Corres Mtg/Teleco Request - Other	MA-Corres; Resp to Re Info	MA-Corresi General Corresp	MA-Corres Request Other	MA-Corres Mig/Teleco Request for Meeting
22-Dec-05	28-Dec-05	29-Dec-05	31-Dec-05	11-Jan-06	20-Jan-06	20-Jan-06	23-Jan-06	23-Jan-06
167099 UNITED STATES	167350 UNITED STATES	167351 UNITED STATES	167352 UNITED STATES	167696 UNITED STATES	168112 UNITED STATES	208335 UNITED STATES	188114 UNITED STATES	168130 UNITED STATES

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Wyeth	FDA	3-Feb-06 FDA	3-Feb-06 Wyeth	Wyeth	Wyeth	6-Feb-06 FDA	7-Feb-06 Wyeth	Wyeth
Pilot Program.	eCTD sequence No. 0001 - Pilot program.	Question and comments regarding the meeting logistics.	8-FEB-2006 meeting.	Pilot Program meeting.	Pilot Program s meeting.	Permission to enter the conference room 10-15 minutes earlier.	Room reservation made earlier than scheduled meeting time.	Coordinate submission package for the 8-MAR-2006 meeting.
CMC Issues	MA-Corres Mtg/Teleco Request for Meeting	o Other	ke Info	CMC Issues	Pilot Pro Meeting Sched/Issues meeting.	Other	ke Other	CMC Issues
MA-FDA C. Phone	MA-Сопея Mtg/Telec	MA-Corres; Mtg/Teleco Other	MA-Corres Resp to Re Info	MA-FDA C. Phone	MA-FDA C.Phone	MA-Corresi Request	MA-Corres _i Resp to Re Other	MA-FDA C-Phone
1-Feb-06	1-Feb-06	3-Feb-06	3-Feb-06	3-Feb-06	3-Feb-06	6-Feb-06	7-Feb-06	9-Feb-06
168828 UNITED STATES	168794 UNITED STATES	168849 UNITED STATES	168939 UNITED STATES	168934 UNITED STATES	168934 UNITED STATES	168940 UNITED STATES	169110 UNITED STATES	169303 UNITED STATES

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Agency's request for raw data sets.	Approval of Dual proprietary name.	8-MAR-2006.	CMC Pilot Program meeting scheduled 8- MAR-06.	Agency's request for raw data sets.	Meeting to discuss Agency's questions.	8-MAR-2006 & 13- APR-2006.	Discuss Wyeth response to the Agency's questions.	Agency's request for raw data sets.
CMC Issues	Other	co Confirm	co Background Pkg	CMC Issues	CMC Issues	sco Confirm	CMC Issues	CMC Issues
MA-FDA C. Phone	MA-Corres Request	MA-Corres Mtg/Teleco Confirm	MA-Corres; Mtg/Teleco Background Pkg	MA-FDA C. Phone	MA-FDA C. Phone	MA-Corres Mig/Teleco Confirm	MA-FDA C. Phone	MA-FDA C. Phone
10-Feb-06	14-Feb-06	16-Feb-06	16-Feb-06	17-Feb-06	17-Feb-06	23-Feb-06	24-Feb-06	24-Feb-06
169719 UNITED STATES	169666 UNITED STATES	171268 UNITED STATES	169644 UNITED STATES	169796 UNITED STATES	169797 UNITED STATES	170047 UNITED STATES	170274 UNITED STATES	170290 UNITED STATES

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Wyeth	27-Feb-06 Wyeth	Wyeth	28-Feb-06 FDA	3-Mar-06 Wyeth	Wyeth	FDA	7-Mar-06 FDA	FDA
Filing communication.		FDA CMC Pilot program meeting scheduled for 8-MAR- 2006.	List of attendees for 8- MAR-2006 meeting.	List of attendees for meeting 8-MAR-2006.	Environmental assessment section for NDA.	Raw data sets used to develop the IVIVC. eCTD sequence 0004.	Copies of the presentation.	Confidential and Non- Confidential Environmental Assessment.
MA-Corres Original Ap Other	MA-Corres _i Original Ap Acknowledge Receipt	MA-FDA C. Phone CMC Issues	MA-Corres; Mtg/Teleco Info	MA-Corres; Mtg/Teleco Info	MA-FDA C. Phone CMC Issues	MA-Corres Amendmer Other	MA-Corres; Mtg/Teleco Info	MA-Corres; Amendmer Other
24-Feb-06	27-Feb-06	28-Feb-06	28-Feb-06	3-Mar-06	3-Mar-06	7-Mar-06	7-Mar-06	16-Mar-06
170679 UNITED STATES	170098 UNITED STATES	170451 UNITED STATES	182003 UNITED STATES	170473 UNITED STATES	170875 UNITED STATES	170655 UNITED STATES	182015 UNITED STATES	171345 UNITED STATES

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Wyeth	Wyeth	FDA	Wyeth	Wyeth	Wyeth	FDA	Wyeth	FDA
16-Mar-06 FDA	Wyeth	24-Mar-06 Wyeth	24-Mar-06 FDA	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth
Pilot program meeting 8-MAR-2006.	Drug product samples for reviewer.	Updated version of slides for meeting 8-Mar-2006. Also need samples of each strength.	Copy of slides presented at 8-Mar- r 2006 meeting.	Clinical Pharmacology Review.	Pilot program meeting 13-APR-2006.	weeting retu c-works 2006 to discuss additional CMC information as part of the CMC pilot program.	Clinical site and sponsor inspections.	Provide answers to aid in the review of the application.
o Minutes	CMC Issues	o Request - Other	Copy of slides presented at 8-Mar-MA-Corres Mtg/Teleco Req Response-Other 2006 meeting.	Clinical Issues	CMC Issues	co Minutes	Clinical Issues	Info
MA-Corres Mig/Teleco Minutes	MA-FDA C. Phone	MA-Corres Mtg/Teleco Request - Other	MA-Corresi Mtg/Telec	MA-FDA C. Phone	MA-FDA C. Phone	MA-Corres Mig/Teleco Minutes	MA-FDA C. Phone	MA-Corres Request
16-Mar-06	24-Mar-06	24-Mar-06	24-Mar-06	7.Apr-06	7.Apr-06	7-Apr-06	10-Apr-06	11-Apr-06
171423 UNITED STATES	172309 UNITED STATES	172158 UNITED STATES	172162 UNITED STATES	172825 UNITED STATES	172826 UNITED STATES	173287 UNITED STATES	172986 UNITED STATES	173018 UNITED STATES

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NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992				
Wyeth	Wyeth	FDA	Wyeth	FDA	Wyeth	Wyeth	Wyeth	FDA
FDA	FDA	25-Apr-06 Wyeth	25-Apr-06 FDA	25-Apr-06 Wyeth	25-Apr-06 FDA	Wyeth	FDA	Wyeth
Four Month update.	Data from clinical investigators who participated in the study.	Acknowledged receipt of the 1572s.	Recent submissions.	Recent submissions issues. 21-APR-2006 submission is not yet available.	Provide the 1572s requested by the Agency.	QBR template questions.	Provide comparability protocol for the implementation of PAT.	
MA-Corres; Safety Upd Other	MA-Corresi Resp to Re Info	MA-Corresj General Corresp	MA-Corresj General Corresp	MA-Corresi Resp to Re Info	MA-Corresi Resp to Re Info	MA-FDA C-Phone Other	MA-Corres; Amendmer Other	MA-Corres Resp to Re Review/Comment
21-Apr-06	21-Apr-06	25-Apr-06	25-Apr-06	25-Apr-06	25-Apr-06	27-Apr-06	28-Apr-06	5-Way-06
173614 UNITED STATES	173615 UNITED STATES	173871 UNITED STATES	173873 UNITED STATES	173895 UNITED STATES	173880 UNITED STATES	174224 UNITED STATES	174176 UNITED STATES	174798 UNITED STATES

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DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)								
NDA 21-992								
Wyeth	Wyeth	FDA	FDA	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth
8-May-06 FDA	8-May-06 FDA	8-May-06 Wyeth	9-May-06 Wyeth	FDA	Wyeth	FDA	18-May-06 FDA	FDA
Official user fee action date.	Copy of the IR letter.	IR letter issued on 5- MAY-2006.	User fee action date is 22-OCT-2006.	Completed question based review template.	Pilot program meeting 23-MAY-2006.	Replacement of damaged media.	QBR template response.	(5) compact disc review copies of the 10-MAY-2006 submission.
MA-User Finformation-Request	MA-Corres Request Info	MA-Corres Resp to Re Info	MA-Corresi Resp to Re Info	MA-Corres; Amendmer Issues	MA-FDA C. Phone CMC Issues	MA-Corres General Corresp	MA-Corres General Corresp	MA-Corres, Resp to Re Info
8-May-06	8-May-06	8-May-06	9-May-06	10-May-06	16-May-06	17-May-06	18-May-06	22-May-06
174764 UNITED STATES	208584 UNITED STATES	174784 UNITED STATES	174861 UNITED STATES	174879 UNITED STATES	175432 UNITED STATES	175284 UNITED STATES	175343 UNITED STATES	175566 UNITED STATES

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NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992
Wyeth	FDA	FDA	Wyeth	FDA	Wyeth	Wyeth	Wyeth	Wyeth
22-May-06 FDA	22-May-06 Wyeth	6-Jun-06 Wyeth	Wyeth	7-Jun-06 Wyeth	FDA	9-Jun-06 FDA	FDA	Wyeth
Replacement of CD.	5 CD copies of the 10- MAY-2006 submission.	Requesting a copy of Data sets for 2-year carcinogenicity studies.	Discuss questions on NIVC.	Stat requestsi.	Tradename request: Elifore.	Miscellaneous issues.	Mice and rats carcinogenicity spor studies.	Request for recalculation of IVIVC data.
Corresp	Info	Info	CMC Issues	Info	Corresp	Сопеѕр	Mice an carcinog Data Sets Req-Respor studies.	CMC Issues
MA-Corresp General Corresp	MA-Corres; Request	MA-Corres Request	MA-FDA C. Phone	MA-Corresj Request	MA-Corres General Corresp	MA-Corres; General Corresp	MA-Corres _i Data	MA-FDA C. Phone
22-May-06	22-May-06	90-unr-9	7-Jun-06	7-Jun-06	7-Jun-06	90-Jun-06	90-unf-6	12-Jun-06
176104 UNITED STATES	207881 UNITED STATES	176455 UNITED STATES	176583 UNITED STATES	176594 UNITED STATES	176572 UNITED STATES	176706 UNITED STATES	176701 UNITED STATES	176946 UNITED STATES

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DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)					
NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992					
Wyeth	Wyeth	FDA	FDA	Wyeth	FDA	Wyeth	Wyeth	Wyeth
15-Jun-06 FDA	15-Jun-06 FDA	15-Jun-06 Wyeth	16-Jun-06 Wyeth	16-Jun-06 FDA	21-Jun-06 Wyeth	21-Jun-06 FDA	FDA	26-Jun-06 Wyeth
September's advisory committee.	September's advisory committee.		Questions regarding blood pressure.	Advisory committee information.	Need to follow the guidance on page 61. 2- yr carcinogenicity studies.	Carcinogenicity studies.	September advisory committee meeting background information.	Investigator files associated with study 306.
MA-Corres Request Info	MA-Corres General Corresp	MA-Corres General Corresp	MA-Corres Resp to Re Info	MA-Corres Request Info	MA-Corres Report [Noi Other	MA-Corres Request Info	MA-Corres Request Info	MA-Corres Inspection Notice
15-Jun-06	15-Jun-06	15-Jun-06	16-Jun-06	16-Jun-06	16-Jun-06	21-Jun-06	22-Jun-06	26-Jun-06
177288 UNITED STATES	177289 UNITED STATES	177291 UNITED STATES	177487 UNITED STATES	177486 UNITED STATES	177570 UNITED STATES	177665 UNITED STATES	177753 UNITED STATES	177852 UNITED STATES

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DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)								
NDA 21-992								
Wyeth	FDA	FDA	FDA	Wyeth	FDA	Wyeth	Wyeth	Wyeth
FDA	26-Jun-06 Wyeth	27-Jun-06 Wyeth	28-Jun-06 Wyeth	FDA	6-Jul-06 Wyeth	6-Jul-06 FDA	7-Jul-06 FDA	7-Jul-06 FDA
Recalculated IVIVC information.	Care Data Set qyestions and responses.		Stat request.	Minor amendment CMC.		Feedback regarding medical questions.	Information will be provided next week.	Inform the Agency eCTD has been loaded into the server.
MA-Corres, Amendmer Other	MA-Corresi Resp to Re Info	MA-Corresi Request Info	MA-Corresj Request Info	MA-Corres Resp to Reinfo	MA-Corres Request Info	MA-Corresj Request Guidance	MA-Corresj Resp to Re Info	MA-Corres General Corresp
26-Jun-06	26-Jun-06	27-Jun-06	28-Jun-06	3-14-06	90-Inf-9	90-101-06	7-Jul-06	7-341-06
177862 UNITED STATES	178420 UNITED STATES	178415 UNITED STATES	178458 UNITED STATES	178397 UNITED STATES	178624 UNITED STATES	178645 UNITED STATES	178625 UNITED STATES	178649 UNITED STATES

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DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)								
NDA 21-992								
Wyeth	Wyeth	FDA	FDA	FDA	FDA	Wyeth	Wyeth	FDA
7-Jul-06 FDA	10-Jul-06 FDA	10-Jul-06 Wyeth	10-Jul-06 Wyeth	12-Jul-06 Wyeth	13-Jul-06 Wyeth	FDA	14-Jul-06 FDA	14-Jul-06 Wyeth
Carcinogenicity data sets.	Re-confirmed NDA numbers.	Clarification of NDA numbers.	Correction - Typographical error.	Revised version of the requests for info.	Reminder to send list of investigators/Briefing materials.	Response to statistical queries.	Statistical queries.	
MA-Corres Request Info	MA-Corres; General Corresp	MA-Corres General Corresp	MA-Corresi General Corresp	MA-Corresi General Corresp	MA-Corres Mig/Teleco Request - Other	MA (Pend): Clinical	MA-Corres Resp to Re Other	MA-Corres; Fed Regist Other
90-10ר-7	10-Jul-06	10-Jul-06	10-Jul-06	12-Jul-06	13-Jul-06	13-Jul-06	14-Jul-06	14-Jul-06
178646 UNITED STATES	178862 UNITED STATES	178864 UNITED STATES	178867 UNITED STATES	178856 UNITED STATES	178969 UNITED STATES	178910 UNITED STATES	179047 UNITED STATES	17948B UNITED STATES

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NDA 21-992								
FDA	FDA	FDA	Wyeth	Wyeth	FDA	Wyeth	FDA	Wyeth
17-Jul-06 Wyeth	20-Jul-06 Wyeth	27-Jul-06 Wyeth	27-Jul-06 FDA	27-Jul-06 FDA	27-Jul-06 Wyeth	FDA	2-Aug-06 Wyeth	FDA
Minutes of 23-MAY- 2006.	Meeting date changed to 7-SEP- 2006.	Requesting Carcinogenicity Data sets.	Expect to send the Carcinogenicity Data Sets Monday 31-JUL-2006.	Acknowledged receipt of date change.	Date for meeting has been changed to 7- SEPT-2006.	Re-submission of mouse and rat Carcinogenicity datasets.	CAC Data Sets.	7-SEP-2006 PDAC meeting.
MA-Corres; Mtg/Teleco Minutes	MA-Corres; Mtg/Teleco Info	MA-Corres Request Info	MA-Corres Resp to ReInfo	MA-Corresj Mtg/Teleco Other	MA-Corres _i Mtg/Teleco Info	MA-Corres Amendmer Other	MA-Corres General Corresp	MA-Corres; Mtg/Teleco Background Pkg
17-Jul-06	20-Jul-06	27-Jul-06	27-Jul-06	27-Jul-06	27-Jul-06	31-Jul-06	2-Aug-06	3-Aug-06
179236 UNITED STATES	179430 UNITED STATES	179827 UNITED STATES	179828 UNITED STATES	179877 UNITED STATES	179875 UNITED STATES	179953 UNITED STATES	180145 UNITED STATES	180380 UNITED STATES

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NE SUCCINATE
(MAJOR
DEPRESSIVE
DISORDER) |
| NDA 21-992 |
Wyeth	Wyeth	FDA	FDA	Wyeth	FDA	FDA	FDA	Wyeth
7-Aug-06 FDA	7-Aug-06 FDA	7-Aug-06 Wyeth	7-Aug-06 Wyeth	7-Aug-06 FDA	7-Aug-06 Wyeth	7-Aug-06 Wyeth	7-Aug-06 Wyeth	9-Aug-06 FDA
Population PK analyses.	Briefing book for 7- SEP-2006 Advisory Committee Meeting.	Agency will confirm package arrival.	Resend and/or fax Investigator/Briefing materials.			Population PK feedback issues.	Statistical analyses of studies 309 and 320.	Population PK feedback
MA-Corres Clinical Iss. Other	MA-Corres Mg/Teleco Info	MA-Corres General Corresp	MA-Corres Request Info	MA-Corres; General Corresp	MA-Corres General Corresp	MA-Corres _i Clinical Iss Other	MA-Corres Request Info	MA-Corres General Corresp
7-Aug-06	9-Aug-06							
180525 UNITED STATES	180526 UNITED STATES	180571 UNITED STATES	180572 UNITED STATES	180573 UNITED STATES	180574 UNITED STATES	180575 UNITED STATES	180576 UNITED STATES	180816 UNITED STATES

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FDA	Wyeth	Wyeth	FDA	FDA	FDA	Wyeth	Wyeth	FDA
11-Aug-06 Wyeth	FDA	21-Aug-06 FDA	21-Aug-06 Wyeth	21-Aug-06 Wyeth	25-Aug-06 Wyeth	28-Aug-06 FDA	Wyeth	29-Aug-06 Wyeth
Message from Yaning.	7-SEP-2006 Drug Advisory Committee Issue meeting.	Assembly of data sets.	Telephone information for the teleconference.	List of attendees.	Extension letter.	Formatting issues. FDA request for raw	data sets and electronic copy of presentation during the pre-approval inspection of Guyama.	Datasets appear to be Data Sets Req-Respor acceptable.
Corresp	7-SEP-2 Advisory MA-Corres Mtg/Teleco Background Pkg-issue meeting.	Сопеѕр	co Info	co Info	Corresp	Сотеѕр	CMC Issues	Data Sets Req-R
MA-Corresj General Corresp	MA-Corres Mtg/Fele	MA-Corresj General Corresp	MA-Corres; Mtg/T eleco Info	MA-Corres; Mtg/T eleco Info	MA-Corres General Corresp	MA-Corres General Corresp	MA-FDA C. Phone	MA-Corres _i Data
11-Aug-06	16-Aug-06	21-Aug-06	21-Aug-06	21-Aug-06	25-Aug-06	28-Aug-06	28-Aug-06	29-Aug-06
181486 UNITED STATES	181223 UNITED STATES	181424 UNITED STATES	181479 UNITED STATES	181476 UNITED STATES	181848 UNITED STATES	181949 UNITED STATES	181941 UNITED STATES	182009 UNITED STATES

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DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)				
NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992				
Wyeth	Wyeth	FDA	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth
Wyeth	30-Aug-06 FDA	31-Aug-06 Wyeth	FDA	1-Sep-06 FDA	5-Sep-06 FDA	5-Sep-06 FDA	5-Sep-06 FDA	5-Sep-06 FDA
	Various issues.	DPP has extended the UF date by 3 months.	Response to request for statistical analyses.	Electronic copies of the pre-approval inspection in Guyama, PR.	PAI introductory presentation - part 1.	PAI introductory presentation - part 2.	PAI introductory presentation - part 3.	PAl introductory presentation - part 4.
MA-FDA C. Phone Non-Clinical Issues	MA-Corres General Corresp	MA-Corres General Corresp	MA-Corres Amendmer Other	MA-Corresi Mtg/Teleco Info	MA-Corresj General Corresp	MA-Corres; General Corresp	MA-Corresi General Corresp	MA-Corres, General Corresp
29-Aug-06	30-Aug-06	31-Aug-06	31-Aug-06	1-Sep-06	90-deS-5	5-Sep-06	5-Sep-06	90-deS-S
182046 UNITED STATES	182142 UNITED STATES	182140 UNITED STATES	182310 UNITED STATES	182347 UNITED STATES	182419 UNITED STATES	182422 UNITED STATES	182424 UNITED STATES	182425 UNITED STATES

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Wyeth	FDA							
5-Sep-06 FDA	5-Sep-06 FDA	5-Sep-06 FDA	FDA	14.Sep-06 FDA	FDA	18-Sep-06 FDA	19-Sep-06 FDA	19-Sep-06 Wyeth
PAI introductory presentation - part 1a.	PAI introductory presentation - parl 4a.	PAI introductory presentation - parl 4b.	Nonmen Gode and Data Sets.	Status of submissions.	Correction of population pharmacokinetics calculations.	Withdraw request for dual tradename and proprietary name	Feedback on the dual trade name proposal. 19-Sep-06 FDA	
MA-Corres General Corresp	MA-Corresi General Corresp	MA-Corres General Corresp	MA-Corres; Resp to Re Info	MA-Corresp Resp to Re Info	MA (Pend). Request-Response	MA-Corres General Corresp	MA-Corres; Request Info	MA-Corres Resp to Re Info
5-Sep-06	5-Sep-06	5-Sep-06	. 90-deS-5	14-Sep-06	14-Sep-06	18-Sep-06	19-Sep-06	19-Sep-06
182426 UNITED STATES	182427 UNITED STATES	182428 UNITED STATES	182441 UNITED STATES	183083 UNITED STATES	183122 UNITED STATES	183292 UNITED STATES	183414 UNITED STATES	183415 UNITED STATES

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DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)								
NDA 21-992								
Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	FDA	Wyeth	Wyeth	FDA
20-Sep-06 FDA	Wyeth	21-Sep-06 FDA	FDA	23-Sep-06 FDA	25-Sep-06 Wyeth	FDA	27-Sep-06 FDA	27-Sep-06 Wyeth
NDA review status.	Status of review.	Dual trade names for VMS and MDD	Efficacy and Safety information and analyses.	Status and Carcinogenicity review.	Status and carcinogenicity review.	Withdrawal of Elifore as proposed trade name.	Inform the Agency of the Carcinogenicity submission.	Confirmed receipt of e- mail.
MA-Corres Original Ap Other	MA-FDA C. Phone CMC Issues	MA-Corres Resp to Re Other	MA-Corres; Resp to Re Info	MA-Corresj Request Info	MA-Corres Resp to Re Info	MA (Pend). Other	MA-Corresy General Corresp	MA-Corres General Corresp
20-Sep-06	20-Sep-06	21-Sep-06	22-Sep-06	23-Sep-06	25-Sep-06	26-Sep-06	27-Sep-06	27-Sep-06
183442 UNITED STATES	183436 UNITED STATES	183744 UNITED STATES	183602 UNITED STATES	183607 UNITED STATES	183702 UNITED STATES	183802 UNITED STATES	183884 UNITED STATES	183885 UNITED STATES

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DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)					
NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992					
Wyeth	FDA	Wyeth	Wyeth	Wyeth	FDA	FDA	Wyeth	Wyeth
27-Sep-06 FDA	Wyeth	FDA	FDA	3-Oct-06 FDA	Wyeth	3-Oct-06 Wyeth	4-Oct-06 FDA	10-Oct-06 FDA
Confirmed the last labeling submission dated 21-APR-2006.					Agency is looking for the open label exposure for the B group.	Need new carton and container for the new proposed name Pristin.	Dates for exposure information and bottle labeling submission.	Exposure information. 10-Oct-06 FDA
MA-Corres Labeling Other	MA-Corres Resp to Re Info	MA-Corres Request Info	MA-Corres Request Info	MA-Corresi Request Info	MA-Corres; Resp to ReInfo	MA-Corresj Request Info	MA-Corres Resp to ReInfo	MA-Corres Resp to ReInfo
27-Sep-06	2-0ct-06	2-04-06	2-Oct-06	3-00-06	3-Oct-06	3-00-08	4-0ct-06	10-001-06
18386 UNITED STATES	184285 UNITED STATES	184284 UNITED STATES	184283 UNITED STATES	184312 UNITED STATES	184313 UNITED STATES	184346 UNITED STATES	18414 UNITED STATES	184761 UNITED STATES

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DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)					
NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992					
Wyeth	Wyeth	Wyeth	FDA	FDA	Wyeth	Wyeth	Wyeth	Wyeth
FDA	FDA	13-Oct-06 FDA	16-Oct-06 Wyeth	17-Oct-06 Wyeth	18-Oct-06 FDA	Wyeth	25-Oct-06 FDA	FDA
Exposure year data for integrated safety groups B1, B2 and C.	Blister, bottle and carton labeling.	Requested revised labels were submitted Thursday, 12-0CT-2006.	Acknowledged receipt of revised labels.	P/T information.	Requested information will be provided to the Agency by 30-OCT-2006.	Status of review of the CMC sections.	Technical part of the response.	Historical Control Data.
MA (Pend) Clinical	MA (Pend). Labeling	MA-Corres Labeling Other	MA-Corres, General Corresp	MA-Corres; Request Info	MA-Corres Resp to Re Other	MA-FDA C. Phone CMC Issues	MA-Corres, Resp to Re Info	MA-Corres Resp to Re Info
10-Oct-06	12-Oct-06	13-Oct-06	16-Oct-06	17-Oct-06	18-Oct-06	25-Oct-06	25-Oct-06	26-Oct-06
184779 UNITED STATES	184981 UNITED STATES	185123 UNITED STATES	185124 UNITED STATES	185311 UNITED STATES	185529 UNITED STATES	185998 UNITED STATES	186178 UNITED STATES	186179 UNITED STATES

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NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992					
Wyeth	Wyeth	FDA	Wyeth	FDA	Wyeth	Wyeth	Wyeth	Wyeth
FDA	1-Nov-06 FDA	Vvyeth	Vvyeth	17-Nov-06 Wyeth	Wyeth	Vvyeth	FDA	FDA
cGMP inspection update.	Guyama, PR manufacturing facility. 1-Nov-06 FDA	CMC Section.	Request for CMC	Tradename for DVS.	CMC Pilot Program meeting scheduled for as 30-NOV-2006.	Tradename and review status.	Request comments on proposed logo.	
	on Issues	Info	Request for CA Meeting Sched/Issues Pilot Program.	Corresp	CMC Pilot Prog meeting sched Meeting Sched/Issues 30-NOV-2006.	General	. Review/Comment	-Response
MA (Pend): CMC	MA-Corresi Inspection Issues	MA-Corres Request	MA-FDA C. Phone	MA-Corres General Corresp	MA-FDA C Phone	MA-FDA C. Phone	MA-Corres Request	MA (Pend). Request-Response
1-Nov-06	1-Nov-06	6-Nov-06	17-Nov-06	17-Nov-06	20-Nov-06	22-Nov-08	29-Nov-06	8-Dec-06 A-
186605 UNITED STATES	186589 UNITED STATES	188994 UNITED STATES	187900 UNITED STATES	187885 UNITED STATES	187955 UNITED STATES	188307 UNITED STATES	188889 UNITED STATES	189178 UNITED STATES

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NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992
Wyeth	Wyeth	FDA	Wyeth	Wyeth	Wyeth	FDA	FDA	FDA
Wyeth	12-Dec-06 FDA	15-Dec-06 Wyeth	Wyeth	19-Dec-06 FDA	3-Jan-07 FDA	20-Dec-06 Wyeth	Wyeth	Wyeth
Review status and trade name information.	Concurrence sought for FDA's Antidepressant Written Request Standard.	Written request template not available at this time.		Written request template.	Minutes of 15-NOV- 2006 and 30-NOV- 2006.		Tradename issues.	
General	Concurrence	e Info	CMC Issues	E: Issues	o Minutes	senssi	MA-Corres _i Promotions Info Request-Respon Tradename issues.	Trade Name Issues
MA-FDA C.Phone	MA-Corres Request	MA-Corres Resp to Re Info	MA-FDA C. Phone	MA-Corres _i Pediatric E: Issues	MA-Corres; Mtg/Teleco Minutes	MA-Corres Labeling	MA-Corres Promotion	MA-Corres Labeling
12-Dec-06	12.Dec-06	15-Dec-06	18-Dec-06	19-Dec-06	19-Dec-06	20-Dec-06	21-Dec-06	21-Dec-06
189612 UNITED STATES	189548 UNITED STATES	190354 UNITED STATES	189786 UNITED STATES	190380 UNITED STATES	190241 UNITED STATES	190393 UNITED STATES	190328 UNITED STATES	19049 UNITED STATES

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DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)
NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992
FDA	FDA	Wyeth	Wyeth	FDA	Wyeth	FDA	FDA	Wyeth
22-Dec-06 Wyeth	9-Jan-07 Wyeth	Wyeth	12-Jan-07 FDA	17-Jan-07 Wyeth	17-Jan-07 FDA	Wyeth	22-Jan-07 Wyeth	FDA
	FDA will probably not act on this NDA until 22-JAN-2007.	Clarification of action date and November 1 communication on CGMP inspection.	Minutes from the 11- JAN-2007.	Voice mail message.			Copy of action letter.	Response to approvable letter.
MA-Corresi Pediatric E. Issues	MA-Corresi Resp to Re Info	MA-FDA C. Phone CMC Issues	MA-Соттеs Mig/Teleco Minutes	MA-Corres; Resp to Re Info	MA-Corresi General Corresp	MA-Corres _i Action Lettr Approvable-Orig App	MA-Corresi General Corresp	MA-Corres Intent to Amend
22-Dec-06	9-Jan-07	10-Jan-07	12-Jan-07	17-Jan-07	17-Jan-07	22-Jan-07	22-Jan-07	25-Jan-07
190411 UNITED STATES	190759 UNITED STATES	191069 UNITED STATES	191005 UNITED STATES	191246 UNITED STATES	191248 UNITED STATES	192069 UNITED STATES	191506 UNITED STATES	191727 UNITED STATES

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DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)								
NDA 21-992								
Wyeth	Wyeth	FDA	Wyeth	Wyeth	Wyeth	FDA	Wyeth	Wyeth
Wyeth	29-Jan-07 FDA	29-Jan-07 Wyeth	30-Jan-07 FDA	Wyeth	FDA	5-Feb-07 Wyeth	Wyeth	7-Feb-07 FDA
	Resubmission classification questions.	Resubmission classification questions.	Combined labeling for both indications MDO and VMS.		Clarification to comment #5 under CMC section.	Label alignment.		Additional questions.
MA-FDA C Phone CMC Issues	MA-Corres General Corresp	MA-Corresi Resp to Re Info	MA-Corres Labeling Issues	MA-FDA C. Phone CMC Issues	MA-Corres Resp to ReInfo	MA-Corres Resp to Re Info	MA-FDA C Phone CMC Issues	MA-Corres Labeling Issues
26-Jan-07	29-Jan-07	29-Jan-07	30-Jan-07	30-Jan-07	2-Feb-07	5-Feb-07	5-Feb-07	7-Feb-07
191815 UNITED STATES	191902 UNITED STATES	191962 UNITED STATES	192112 UNITED STATES	192208 UNITED STATES	192339 UNITED STATES	192374 UNITED STATES	192589 UNITED STATES	192593 UNITED STATES

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y∈FDA	Wyeth	FDA	Wyeth	Wyeth	FDA	FDA	FDA	Wyeth
9-Feb-07 W-AL (WyeFDA	22-Feb-07 FDA	Wyeth	1-Mar-07 FDA	2-Mar-07 FDA	5-Mar-07 Wyeth	7-Mar-07 Wyeth	8-Mar-07 Wyeth	FDA
Labeling alignment and additional questions.	Risk Management Plan Questions.	Clarification on what the Reference Listed Drug Name would be.	Risk management plan questions.	Responses to Approvable Letter.	Responses to the approvable letter.	Risk Management Plan Questions were forwarded to the reviewers.	Risk Management Questions information.	
MA-Corres Resp to Re Info	MA-Corres Request Info	MA-Corres, CMC Issues	MA-Corres Request Info	MA-Corres Clinical Issi Info-Request	MA-Corres Resp to Re Info	MA-Corres General Corresp	MA-Corresi General Corresp	MA (Pend) Request-Response
9-Feb-07	22-Feb-07	27-Feb-07	1-Mar-07	2-Mar-07	5-Mar-07	7-Mar-07	8-Mar-07	4-Apr-07
193202 UNITED STATES	193651 UNITED STATES	194059 UNITED STATES	194068 UNITED STATES	194091 UNITED STATES	194215 UNITED STATES	194353 UNITED STATES	19451 UNITED STATES	196445 UNITED STATES

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DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	DESVENLAFAXI NE SUCCINATE (MAJOR. DEPRESSIVE DISORDER)							
NDA 21-992								
Wyeth	FDA	FDA	Wyeth	FDA	Wyeth	Wyeth	FDA	FDA
10-Apr-07 FDA	30-Apr-07 Wyeth	Wyeth	Wyeth	8-May-07 Wyeth	FDA	15-May-07 FDA	? 21-May-07 Wyeth	Wyeth
Partial response to the approvable letter.	No objections to proposal.		Pilot program meeting to discuss the IR letter.		Pre-operational review of the PAT process in the CMC facility.	Feedback on the embryo-fetal study.	List of attendees for CMC pilot program 22- MAY-2007.	Postmarketing commitment issues.
isi Other	Sar	Info	CMC Issues	co Info	Review/Comment	Info	co Info	Zelnfo
MA-Corres _i Clinical Iss Other	MA-Corres; CMC Issues	MA-Corresj Request	MA-FDA C. Phone	MA-Corres Mtg/TelecoInfo	MA-Corresi Request	MA-Corres Request	MA-Corres Mtg/Teleco Info	MA-Corres, Resp to ReInfo
10-Apr-07	30-Apr-07	3-May-07	8-May-07	8-May-07	11-May-07	15-May-07	21-May-07	30-May-07
196925 UNITED STATES	198858 UNITED STATES	199293 UNITED STATES	199338 UNITED STATES	199265 UNITED STATES	201251 UNITED STATES	199725 UNITED STATES	200417 UNITED STATES	201032 UNITED STATES

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Wyeth	Wyeth	FDA	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	FDA
FDA	7-Jun-07 FDA	7-Jun-07 Wyeth	Wyeth	Wyeth	18-Jun-07 FDA	FDA	FDA	6-Jul-07 Wyeth
CMC information request letter dated 3- MAY-2007.	Requesting time change for teleconference scheduled 13-JUN-2007.	Requested time changed granted to 2:30.		Feedback on the completed Clinical Pharmacology Question.	22-MAY-2207.	Response to approvable letter dated 22-JAN-2007.	Response to approvable letter dated 22-JAN-2007.	Minutes of 22-MAY- 2007.
MA-Corres Resp to Re Info	MA-Corres Mtg/Teleco Other	MA-Corres Mig/Teleco Other	MA-FDA C Phone Clinical Issues	MA-FDA C. Phone Clinical Issues	MA-Corres; Mig/Teleco Minutes	MA-Corres Action Letti Response	MA-Corres CMC ssues	MA-Corres; Mtg/Teleco Minutes
1-Jun-07	7-Jun-07	7-Jun-07	8-Jun-07	14-Jun-07	18-Jun-07	27-Jun-07	27-Jun-07	6-Jul-07
201254 UNITED STATES	201789 UNITED STATES	201791 UNITED STATES	201902 UNITED STATES	202438 UNITED STATES	202516 UNITED STATES	203138 UNITED STATES	203138 UNITED STATES	203683 UNITED STATES

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NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992
Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	FDA	Wyeth	Wyeth	FDA
Wyeth	30-Jul-07 Wyeth	7-Aug-07 Wyeth	FDA	FDA	5-Sep-07 Wyeth	Wyeth	11-0ct-07 FDA	14-Oct-07 Wyeth
Follow-up regarding requests made during pre-operational visits.	Response submission to CMC questions.	Pre-operational visit requested by FDA.	Response to the approvable letter dated 23-JUL-2007.	Complete response to approvable letter dated 22-JAN-2007.	Due date will 29-FEB- 2008.	Response to approvable letter being sent via FDA Gateway.	Various issues.	Various issues.
CMC Issues	CMC Issues	CMC Issues		ReInfo	Re Info	Other	t Info	Reinfo
MA-FDA C.Phone	MA-FDA C.Phone	MA-FDA C. Phone	MA (Pend)-CMC	MA-Corres Resp to Re Info	MA-Corres Resp to Re Info	MA-FDA C Phone	MA-Corres Request	MA-Corres, Resp to Re Info
16-Jul-07	30-Jul-07	7-Aug-07	23-Aug-07	29-Aug-07	5-Sep-07	5-Sep-07	11-0ct-07	14-Oct-07
20455 UNITED STATES	208120 UNITED STATES	206579 UNITED STATES	207799 UNITED STATES	208221 UNITED STATES	208738 UNITED STATES	208741 UNITED STATES	213860 UNITED STATES	213861 UNITED STATES

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DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)								
NDA 21-992								
Wyeth	Wyeth	FDA	FDA	FDA	Wyeth	FDA	Wyeth	FDA
14-0ct-07 FDA	15-Oct-07 FDA	16-Oct-07 Wyeth	Wyeth	15-Nov-07 Wyeth	20-Nov-07 FDA	20-Nov-07 Wyeth	20-Nov-07 FDA	20-Nov-07 Wyeth
	Follow-up on the 29- AUG-2007.		User fee goal date 29- FEB-2008.	Copy of the IR letter. 15-Nov-07 Wyeth	Proprietary name feedback.	Proprietary name feedback.	Proprietary name feedback.	Proprietary name issues.
MA-Corresj General Corresp	MA-Corres; General Corresp	MA-Corres Resp to Re Info	MA-Corres; Action Lettr Approval - Orig App	MA-Corres Request Info	MA-Corres Request Info	MA-Corres _l Resp to Re Info	MA-Corres Request Info	MA-Corresj General Corresp
14-0α-07	15-0α-07	16-0d-07	16-0ct-07	15-Nov-07	20-Nov-07	20-Nov-07	20-Nov-07	20-Nov-07
213862 UNITED STATES	213013 UNITED STATES	213014 UNITED STATES	214267 UNITED STATES	215711 UNITED STATES	216018 UNITED STATES	216019 UNITED STATES	216020 UNITED STATES	216335 UNITED STATES

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NDA 21-992								
Wyeth	Wyeth	FDA	Wyeth	FDA	Wyeth	Wyeth	FDA	Wyeth
27-Nov-07 FDA	29-Nov-07 FDA	30-Nov-07 Wyeth	4-Dec-07 FDA	y 11-Dec-07 Wyeth	11-Dec-07 FDA	. 12-Dec-07 FDA	7. 13-Dec-07 Wyeth	FDA
	Proprietary name feedback request.	Proprietary name issues.	Proprietary name feedback issues.	Exposure data in patient-years for study 332 and 333.		To discuss study 302. 12-Dec-07 FDA	Meeting scheduled 17. JAN-2008.	CMC - Pilot program minutes of the 29- NOV-2007 meeting.
MA-Corres Mig/Teleco Req Response- Other	MA-Corres Request Info	MA-Corres General Corresp	MA-Corres Request Info	MA-Corres Clinical Iss। Info-Request	MA-Corresi Resp to Re Other	MA-Corres; Mtg/Teleco Request for Meeting	MA-Corres; Mtg/Teleco Info	MA-Corres; Mtg/Teleco Minutes
27-Nov-07	29-Nov-07	30-Nov-07	4-Dec-07	11-Dec-07	11-Dec-07	12-Dec-07	13-Dec-07	13-Dec-07
216835 UNITED STATES	217021 UNITED STATES	217310 UNITED STATES	217450 UNITED STATES	219441 UNITED STATES	219442 UNITED STATES	219445 UNITED STATES	219576 UNITED STATES	218725 UNITED STATES

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NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992				
Wyeth	Wyeth	Wyeth	FDA	Wyeth	FDA	Wyeth	Wyeth	Wyeth
14-Dec-07 FDA	14-Dec-07 FDA	FDA	17-Dec-07 Wyeth	17-Dec-07 FDA	18-Dec-07 Wyeth	18-Dec-07 FDA	FDA	20-Dec-07 FDA
List of Wyeth's attendees for the 17-JAN-2008 meeting.		Patient Exposure Year Data.		Confirm that Analyses and Datasets will not be classified as a major amendment.			Ammendment Response to CMC Information Request	Proprietary name issues.
MA-Corres _I Mig/Teleco Info	MA-Corres Resp to Re Info	MA-Corres Clinical Iss Info Req-Response	MA-Corresp Clinical Issi Info-Request	MA-Corresp Clinical Issu Info-Request	MA-Corres General Corresp	MA-Corres General Corresp	MA-Corres CMC Issue Request-Response	MA-Corresj Request Info
14-Dec-07	14-Dec-07	14-Dec-07	17-Dec-07	17-Dec-07	18-Dec-07	18-Dec-07	19-Dec-07	20-Dec-07
219578 UNITED STATES	219351 UNITED STATES	218739 UNITED STATES	219585 UNITED STATES	219628 UNITED STATES	219589 UNITED STATES	219590 UNITED STATES	219079 UNITED STATES	219632 UNITED STATES

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NDA 21-992								
Wyeth	Wyeth	Wyeth	Wyeth	Wyeth	FDA	Wyeth	FDA	Wyeth
FDA	21-Dec-07 FDA	4-Jan-08 FDA	7-Jan-08 FDA	Wyeth	11-Jan-08 Wyeth	11-Jan-08 FDA	11-Jan-08 Wyeth	11-Jan-08 FDA
Information regarding studies 332 and 333.		Relapse Position Paper.	Proposed Tradename.	Status of the Agency review of 19-DEC- 2007.	Proprietary information issues.	Proprietary information issues.	Proprietary information.	
is Clinical Issi Info Req-Response	is General Corresp	is General Corresp	Si Request Info	C. Phone CMC Issues	si Resp to Re Info	ss Request Info	si Resp to Reinfo	MA-Corres General Corresp
MA-Corres	MA-Corres	MA-Corresi	MA-Corresi	MA-FDA C	MA-Corresi	MA-Corresi	MA-Corress	MA-Corre
20-Dec-07	21-Dec-07	4-Jan-08	7-Jan-08	8-Jan-08	11-Jan-08	11-Jan-08	11-Jan-08	11-Jan-08
219339 UNITED STATES	219633 UNITED STATES	220173 UNITED STATES	220162 UNITED STATES	220378 UNITED STATES	220744 UNITED STATES	220745 UNITED STATES	220759 UNITED STATES	220760 UNITED STATES

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NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992					
Wyeth	Wyeth	FDA	FDA	Wyeth	Wyeth	FDA	FDA	Wyeth
FDA	15-Jan-08 FDA	17-Jan-08 Wyeth	17-Jan-08 Wyeth	17-Jan-08 FDA	Wyeth	Wyeth	25-Jan-08 Wyeth	26-Jan-08 FDA
Relapse Prevention Position Paper.	List of attendees for the 17-JAN-2008 meeting.	List of attendees. DMETS review found name acceptable.	List of attendees. DMETS review found name acceptable.	Tradename questions.	Acceptability of the Randomized Meeting Sched/Issues Withdraw Study.	RiskMap plan.	Copy of RiskMap letter.	Confirm receipt of letter - RiskMap.
MA (Pend)-Other	MA-Corresj Mtg/Teleco Info	MA-Corres Mtg/Teleco Info	MA-Corres; Resp to Re Info	MA-Corres General Corresp	MA-FDA C-Phone Meeting Sched/Iss	MA-Corresj Request Info	MA-Corresi General Corresp	MA-Corres General Corresp
14-Jan-08	15-Jan-08	17-Jan-08	17-Jan-08	17-Jan-08	17-Jan-08	25-Jan-08	25-Jan-08	26-Jan-08
220903 UNITED STATES	221052 UNITED STATES	221493 UNITED STATES	221493 UNITED STATES	221494 UNITED STATES	221555 UNITED STATES	223096 UNITED STATES	222607 UNITED STATES	222626 UNITED STATES

222630 UNITED STATES	29-Jan-08	MA-Corres General Corresp	Response to RiskMAP will probably be submitted this Friday or Monday.	29-Jan-08 FDA	Wyeth	NDA 21-992	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	UNITED S' PRISTIQ	S
223123 UNITED STATES	1-Feb-08	MA-Corres∣Mtg/Tele∞ Info	Questions for teleconference 4-FEB-2008.	1-Feb-08 Wyeth	FDA	NDA 21-992	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	UNITED S'PRISTIQ	sn
223097 UNITED STATES	3-Feb-08	MA-Corres; Mtg/Teleco Info	Dialing info for the teleconference on the 4-FEB-2008.	3-Feb-08 FDA	Wyeth	NDA 21-992	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	UNITED S'PRISTIQ	SN
223130 UNITED STATES	4-Feb-08	MA-Corres Request Info		4-Feb-08 FDA	Wyeth	NDA 21-992	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	UNITED S'PRISTIQ	sn
223132 UNITED STATES	4-Feb-08	MA-Corres Resp to ReInfo		4-Feb-08 Wyeth	FDA	NDA 21-992	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	UNITED S' PRISTIQ	sn
222864 UNITED STATES	4-Feb-08	MA (Pend). Request-Response	Questions concerning RiskMAPs.	FDA	Wyeth	NDA 21-992	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	UNITED S' PRISTIQ	s
223266 UNITED STATES	5-Feb-08	MA-Corres Labeling Other		5-Feb-08 FDA	Wyeth	NDA 21-992	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	UNITED S' PRISTIQ	S
223268 UNITED STATES	7.Feb-08	MA-Corres Mtg/Teleco Request - Other		7-Feb-08 FDA	Wyeth	NDA 21-992	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	UNITED S'PRISTIQ	sn
223585 UNITED STATES	7-Feb-08	MA-Corres Labeling Request		Wyeth	FDA	NDA 21-992	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	UNITED S'PRISTIQ	Sn

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NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992					
FDA	Wyeth	Wyeth	FDA	FDA	Wyeth	Wyeth	FDA	Wyeth
Wyeth	8-Feb-08 FDA	8-Feb-08 FDA	8-Feb-08 Wyeth	8-Feb-08 Wyeth	8-Feb-08 FDA	FDA	12-Feb-08 Wyeth	12-Feb-08 FDA
	Various issues - Labeling and Phase 4 commitments.		Clarification response.	List of attendees 4- FEB-2008.	CMC pilot program of the unofficial minutes of 4-FEB-2008 meeting.	Pilot Program meeting minutes 4-FEB-2008.		
MA-Corres, Phase IV CInformation-Request	MA-Corres Request Info	MA-Corres General Corresp	MA-Corres Resp to ReInfo	MA-Corres Mtg/TelecoInfo	MA-Corres Mig/Teleco Info	MA-Corres _i Mtg/Teleco Minutes	MA-Corres Labeling Revision - Request	MA-Corres General Corresp
7-Feb-08	8-Feb-08	8-Feb-08	8-Feb-08	8-Feb-08	8-Feb-08	11-Feb-08	12-Feb-08	12-Feb-08
223585 UNITED STATES	223665 UNITED STATES	223666 UNITED STATES	223887 UNITED STATES	223694 UNITED STATES	223607 UNITED STATES	223646 UNITED STATES	223787 UNITED STATES	223788 UNITED STATES

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NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992				
FDA	Wyeth	Wyeth	Wyeth	Wyeth	FDA	Wyeth	Wyeth	Wyeth
12-Feb-08 Wyeth	12-Feb-08 FDA	12-Feb-08 FDA	12-Feb-08 FDA	Wyeth	13-Feb-08 Wyeth	13-Feb-08 FDA	13-Feb-08 FDA	13-Feb-08 FDA
	Update on the Iabeling revisions.		List of attendees for the 15-FEB-2008 teleconference.	Amendment to provide responses to FDA's 1-FEB-2008 e- mail.				
se IV C Other	eling Issues	eling Issues	Teleco Info	ne CMC Issues	aling Request	eling Request-Response	eral Corresp	Teleco Info
MA-Corres Phase IV C Other	MA-Corres Labeling	MA-Corres Labeling	MA-Corres; Mtg/Teleco Info	MA-FDA C. Phone	MA-Corres Labeling	MA-Corres Labeling	MA-Corres General Corresp	MA-Correst Mtg/Teleco Info
12-Feb-08	12-Feb-08	12-Feb-08	12-Feb-08	12-Feb-08	13-Feb-08	13-Feb-08	13-Feb-08	13-Feb-08
223790 UNITED STATES	223791 UNITED STATES	223826 UNITED STATES	223828 UNITED STATES	223984 UNITED STATES	223832 UNITED STATES	223833 UNITED STATES	223978 UNITED STATES	223979 UNITED STATES

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13-Feb-08 Wyeth	13-Feb-08 FDA	-Feb-08	14-Feb-08 FDA	14-Feb-08 FDA	14-Feb-08 Wyeth		15-Feb-08 FDA	15-Feb-08 Wyeth
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		al informa	Commitr ts.			ated 12-f	tendees neeting.	
		Additional information. 13-Feb-08 FDA	Phase 4 Commitment comments.			E-mail dated 12-FEB- 2008.	List of attendees for today's meeting.	
	onse						ā	
	Request-Response					Rev Req - Response	MA-Corres Mtg/Teleco Request - Other	
Other		Other	MA-Corres Clinical Iss Other	Info	Re Info		co Requ	nes
abeling	MA-Corres Labeling	abeling	Clinical Is	MA-Corres Request	Resp to ReInfo	MA-Corres Labeling	Mtg/Tele	MA-Corres CMC ssues
MA-Corres _t Labeling	Correst	MA-Corres Labeling	CorresiC	Сопез	MA-Corres _l F	Correst	Сопея	-Corresi (
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13-Feb-08	13-Feb-08	13-Feb-08	14-Feb-08	14-Feb-08	14-Feb-08	14-Feb-08	15-Feb-08	15-Feb-08
223981 UNITED STATES	223967 UNITED STATES	223974 UNITED STATES	223961 UNITED STATES	223965 UNITED STATES	223966 UNITED STATES	224091 UNITED STATES	224131 UNITED STATES	224400 UNITED STATES
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22398	22396	22397	22396	22396	22396	22409	22413	22440

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| NDA 21-992 |
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Wyeth	FDA	15-Feb-08 Wyeth	15-Feb-08 Wyeth	15-Feb-08 FDA	19-Feb-08 Wyeth	19-Feb-08 FDA	19-Feb-08 FDA	19-Feb-08 FDA
		List of attendees for today's meeting.	Updated adverse events table.					Change - Studies conducted in 8 weeks not 6.
CMC Issues		co Info	Corresp	Rev Req - Response	<u>In</u> fo	Cissues	Cissues	Cissues
MA-FDA C. Phone	MA (Pend): CMC	MA-Corres Mig/Teleco Info	MA-Corres General Corresp	MA-Corresi Labeling	МА-Сотеs Request	MA-Corres Phase IV Cissues	MA-Corres, Phase IV C Issues	MA-Corres _i Phase IV Cissues
15-Feb-08	15-Feb-08	15-Feb-08	15-Feb-08	15-Feb-08	19-Feb-08	19-Feb-08	19-Feb-08	19-Feb-08
224558 UNITED STATES	224112 UNITED STATES	224375 UNITED STATES	224374 UNITED STATES	224373 UNITED STATES	224397 UNITED STATES	224398 UNITED STATES 19-Feb-08	224399 UNITED STATES	224388 UNITED STATES

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DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)								
NDA 21-992								
Wyeth	Wyeth	FDA	Wyeth	FDA	Wyeth	FDA	Wyeth	FDA
19-Feb-08 FDA	Wyeth	19-Feb-08 Wyeth	19-Feb-08 FDA	19-Feb-08 Wyeth	20-Feb-08 FDA	20-Feb-08 Wyeth	20-Feb-08 FDA	20-Feb-08 Wyeth
	FDA's request to remove Impurities test from NDA.	Updated labeling.						
info	CMC Issues	Other	senssi	COther	senssi	Request	Issues	Request-Response
MA-Corres; Request	MA-FDA C. Phone	MA-Corresi Labeling	MA-Corres Labeling	MA-Corres Phase IV C Other	MA-Corresi Labeling	MA-Corresi Labeling	MA-Corresi Labeling	MA-Corres Labeling
19-Feb-08	19-Feb-08	19-Feb-08	19-Feb-08	19-Feb-08	20-Feb-08	20-Feb-08	20-Feb-08	20-Feb-08
224402 UNITED STATES	224557 UNITED STATES	224381 UNITED STATES	224383 UNITED STATES	224384 UNITED STATES	224389 UNITED STATES	224546 UNITED STATES	224548 UNITED STATES	224554 UNITED STATES

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20-Feb-08	MA-C	MA-Corres CMC Issues		Follow-up to telecon. 20-Feb-08 Wyeth	20-Feb-08 Wyeth	FDA	NDA 21-992	NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	UNITED S' PRISTIQ	S)
20-Feb-08 MA-Corresj CMC Issues	orresj CMC Issues			Summary of teleconference 19- FEB-2008.	20-Feb-08 FDA	Wyeth	NDA 21-992	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	UNITED S' PRISTIQ	ns
20-Feb-08 MA-FDA C-Phone Lat		ri i	Labeling	Doc dated 2007 in error.	Wyeth	Wyeth	NDA 21-992	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	UNITED S' PRISTIQ	S
20-Feb-08 MA-FDA C. Phone Other	C. Phone	Othe		Doc dated 2007 in error.	Wyeth	Wyeth	NDA 21-992	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	UNITED S' PRISTIQ	ns
20-Feb-08 MA-Corres Labeling Rev R		Rev R	Rev Req - Response		20-Feb-08 FDA	Wyeth	NDA 21-992	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	UNITED S' PRISTIQ	ns
20-Feb-08 MA-Corresi Resp to Re Info	orres, Resp to Re Info	nfo		CMC correspondence dated 15-FEB-2008.	FDA	Wyeth	NDA 21-992	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	UNITED S' PRISTIQ	Sn
21-Feb-08 MA-Corres Mig/Teleco Request for Meeting	orres∣Mtg/Teleco Reques	Zednes	it for Meeting	Day of approval logistics.	21-Feb-08 FDA	Wyeth	NDA 21-992	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	UNITED S' PRISTIQ	sn
21-Feb-08 MA-FDA C.Phone CMC Issues		CMC Is	sens	Remove impurities tests from NDA.	Wyeth	Wyeth	NDA 21-992	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	UNITED S' PRISTIQ	Sn
21-Feb-08 MA-Corres Labeling Request		Request			21-Feb-08 FDA	Wyeth	NDA 21-992	DESVENLAFAXI NE SUCCINATE (MAJOR DEPRESSIVE DISORDER)	UNITED S' PRISTIQ	Sn

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| NDA 21-992 |
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21-Feb-08 FDA	FDA	22-Feb-08 Wyeth	22-Feb-08 FDA	22-Feb-08 FDA	22-Feb-08 Wyeth	FDA	FDA	26-Feb-08 FDA
Discuss good communication practices.			Minor error in the last paragraph of section 10.	Communication issues.	Minor label correction fixed.			
MA-Corres General Corresp	MA-Corres Labeling Draft	MA-Corres; Resp to ReInfo	MA-Corresi Labeling Issues	MA-Corresi General Corresp	MA-Corres Labeling Issues	MA (Pend). CMC	MA (Pend). Request-Response	MA-Corres Labeling Issues
21-Feb-08	21-Feb-08	22-Feb-08	22-Feb-08	22-Feb-08	22-Feb-08	22-Feb-08	22-Feb-08	26-Feb-08
224585 UNITED STATES	224531 UNITED STATES	224587 UNITED STATES	224588 UNITED STATES	224589 UNITED STATES	224590 UNITED STATES	224594 UNITED STATES	224594 UNITED STATES	224991 UNITED STATES

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NDA 21-992								
Wyeth	Wyeth	FDA	Wyeth	FDA	Wyeth	Wyeth	Wyeth	Wyeth
27-Feb-08 FDA	27-Feb-08 FDA	27-Feb-08 wyeth	28-Feb-08 FDA	28-Feb-08 Wyeth	Wyeth	. 29-Feb-08 FDA	29-Feb-08 FDA	29-Feb-08 FDA
Tradename question. 27-Feb-08 FDA		Updated labeling version.				Request copy of Approval letter ASAP. 29-Feb-08 FDA		Thank you note.
MA-Corres General Corresp	MA-Corres Labeling Issues	MA-Corres Labeling Request	MA-Corres, Phase IV Cissues	MA-Corres Phase IV C Other	MA-FDA C. Phone Labeling	MA-Corres General Corresp	MA-Corres, Labeling Issues	MA-Corres General Corresp
27-Feb-08	27-Feb-08	27-Feb-08	28-Feb-08	28-Feb-08	28-Feb-08	29-Feb-08	29-Feb-08	29-Feb-08
224992 UNITED STATES	225165 UNITED STATES	225042 UNITED STATES	225177 UNITED STATES	225178 UNITED STATES	225166 UNITED STATES	225179 UNITED STATES	225180 UNITED STATES	225219 UNITED STATES

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NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992					
Wyeth	FDA	Wyeth	FDA	Wyeth	Wyeth	Wyeth	Wyeth	Wyeth
29-Feb-08 FDA	Wyeth	FDA	29-Feb-08 Wyeth	FDA	FDA	FDA	FDA	FDA
Thank you note.					Advisory comments.			
опеѕр	t Approval - Orig App	Draft	ıı Approval - Orig App	PPR	MA-Corres _! Promotionɛ information-Request Advisory comments.	www	www	www
MA-Corres, General Corresp	MA-Corres, Action Lettr Approval - Orig App	МА-Согеs Labeling	MA-Corres; Action Lettr Approval - Orig App	MA-Promo Routine	МА-Согеs _! Promotion	MA-Promo Routine	MA-Promo Routine	MA-Promo Routine
29-Feb-08	29-Feb-08	29-Feb-08	29-Feb-08	3-Mar-08 223002-01 MA-Promo Routine	3-Mar-08	3-Mar-08 215956-01 MA-Promo Routine	3-Mar-08 216156-01 MA-Promo Routine	3-Mar-08 223151-01 MA-Promo Routine
225220 UNITED STATES	226310 UNITED STATES	225120 UNITED STATES	225215 UNITED STATES	225281 UNITED STATES	226311 UNITED STATES	225321 UNITED STATES	225322 UNITED STATES	225323 UNITED STATES

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NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992	NDA 21-992
Wyeth	Wyeth	Wyeth	Wyeth	Wyeth
FDA	FDA	4-Mar-08 FDA	FDA	·
		Initial launch campaign material sent to DDMAC.		Provide a copy of the submission to the NDA in eCTD format.
MA-Promo Routine COT	3-Mar-08 224715-01 MA-Promo Routine POT	MA-Corres, Promotions Other	MA-Corres Labeling FPL	MA-Corres General Corresp
3-Mar-08 224485-01 MA-Promo	3-Mar-08 224715-01	4-Mar-08	12-Mar-08	13-Mar-08
225324 UNITED STATES	225325 UNITED STATES	225288 UNITED STATES	226150 UNITED STATES	226281 UNITED STATES